THE OTHER SIDE OF COVID-19 RESEARCH

A SCIENTIFIC, DATA-DRIVEN APPROACH TO VACCINE SAFETY, PANDEMIC RESPONSES, AND POLITICAL AND MEDIA INFLUENCE ON PUBLIC HEALTH

(MAY 2024)

INDEX

NOTE FROM THE AUTHOR

This paper aims to provide a compendium of specialized assessments that counter the conventional discourse surrounding the COVID-19 pandemic responses. The document focuses on highly credible (often silenced) voices in order to cut through the noise of sanctioned interpretations with divergent, sincere, and well-founded perspectives. The purpose of this paper is to offer an alternative overview that transcends imposed narratives, while advocating for transparency, critical thinking, and open discourse.

However, this compendium offers more than a mere alternative viewpoint; it unveils the profound repercussions of a global crisis navigated by untrustworthy entities. It probes the relationships between governments, pharmaceutical giants, and non-elected bodies such as the WHO, exposing the intricate tapestry of influence that permeates policy-making, public health, and individual liberties.

What unfolds throughout is a stark, data-based reminder of the risks entailed in unquestioningly adhering to established ideologies and sanctioned opinions, and the potentially perilous consequences of complacency—of accepting without scrutiny the information disseminated by institutions with vested interests.

In the biopharmaceutical industry, for instance, the normal timeline for developing a complex biomedical product, such as a vaccine, spans several years and involves multiple stages, including discovery, preclinical testing, clinical trials, regulatory approval, and large-scale manufacturing. Typically, the fastest development process on record is six years. Each of these stages requires meticulous planning and testing to ensure safety and efficacy. The methods development alone for a reproducible manufacturing process can take several years.

In contrast, the timeline for the COVID-19 vaccines was significantly accelerated, with development, testing, and global distribution occurring within a much shorter period. This expedited process raises concerns about the thoroughness and safety of the vaccines. The rapid development and deployment imply that the necessary time for rigorous evaluation and long-term studies was not available, leading to potential risks and adverse effects. This stark difference in timelines suggests that the COVID-19 vaccines have not undergone the same level of scrutiny and validation as traditional vaccines, resulting in significant public health implications.

It merits highlighting that pharmaceutical companies are often shielded from litigation even when medical malpractice or negligence occurs, and special clauses related to the creation of COVID-19 vaccines further protect these companies from legal action, effectively granting them immunity from lawsuits arising from adverse effects caused by these vaccines and leaving victims with limited recourse for justice.

Beyond an intellectual exercise, the depth of analysis in this collection serves as a call to vigilance—an invitation to scrutinize, ponder, and safeguard your autonomy in a world where the guise of authority often obscures ulterior motives. This compendium stands as an impassioned plea through dispassionate data to embrace skepticism and discernment, recognizing that the pursuit of truth demands an unwavering commitment to question the supposedly unquestionable.

As the sole creator of this document, I strove to provide a broad, critical, and accurate overview. However, my individual efforts have limitations. I welcome outside input to enrich this compilation with relevant perspectives, address its shortcomings, and strengthen its value. My hope is that this document becomes a useful resource in advocating for transparency, accountability, and for the cultivation of critical thinking.

This document was made to serve Humanity. For this reason, it will remain freely available in perpetuity.

Medical Professionals and Political Representatives

This chapter is a compilation of interventions and perspectives offered by a cohort of distinguished figures: medical luminaries, Nobel laureates, and resolute politicians. These individuals, renowned for their expertise and contributions, step away from their usual roles to challenge the prevailing pandemic narrative.

Their collective insights unearth unsettling revelations—unveiling medical malpractice, health mismanagement, data manipulation, scientific aberrations, and their profound impact on governmental decisions and individual freedoms. What sets their discourse apart is not just the critique but the evidence-backed assertions grounded in their unparalleled experience and expertise.

At the crux of their concerns lies the swift adoption of novel and untested vaccine technologies. Their contention doesn't merely highlight discrepancies; it underscores the glaring disparity between promised safety and the mounting reports of adverse effects, often sidelined or disregarded by official channels. Furthermore, these experts express genuine apprehension about potential long-term health implications stemming from these expedited vaccination campaigns.

This chapter isn't just a critique; it's a stark reminder of the precarious situation when government entities, mainstream media, medical institutions, and pharmaceutical companies wield their influence to manipulate public perception, thereby evading accountability. It's disconcerting when voices of experts raising legitimate concerns are marginalized or silenced, creating a void where crucial insights are overlooked or dismissed. This raises urgent questions about transparency, integrity, and the preservation of public trust within the complex nexus of health, governance, and information dissemination.

Dr. Harvey Risch, ScD, Ph.D.

Website
Google Scholar

- A prominent epidemiologist and professor of epidemiology at the Yale School of Public Health.
- Dr. Risch holds an MD degree, a Doctor of Science (ScD) degree in Epidemiology, and a Ph.D. on Mathematical Modelling of Infectious Epidemics.
- He's a Professor of Epidemiology at Yale School of Public Health, associated with Yale University for many years.
- Dr. Risch has extensive experience and expertise in the field of epidemiology, particularly in areas such as cancer epidemiology, environmental epidemiology, and infectious diseases.
- He has published numerous research articles and papers in reputable peer-reviewed journals. His work often focuses on epidemiological and public health issues. Dr. Risch also served as an editor for several scientific journals, such as the Journal of the National Cancer Institute and Epidemiology.

Dr. Harvey Risch: COVID-19 Vaccine Harms and Pandemic Policy Shifts

WATCH VIDEO

Efficacy of Masking: Dr. Risch discusses a Cochrane Commission study on masking effectiveness for COVID-19. He explains how both randomized trials and a body of evidence from non-randomized studies indicate that masking is ineffective in controlling the spread of the pandemic, a conclusion supported by over 150 studies.

Change in Pandemic Management Strategies: Dr. Risch points out that the pandemic management strategies have changed from what was recommended in earlier papers. He highlights that policies like lockdowns, travel restrictions, and masking, which were earlier considered inadvisable, were implemented without clear scientific evidence in the current pandemic.

Vaccine Efficacy Over Time: Dr. Risch discusses the efficacy of vaccines, particularly mRNA vaccines. He highlights that the initial two-dose regimen showed effectiveness for a period, but after six months, the protection declined significantly, making individuals more susceptible to infection. He also explains that booster doses have been used, but their effectiveness decreases over time as the virus continues to mutate.

Public Health Approach: Dr. Risch questions the approach to managing the pandemic, emphasizing that most people do well with COVID-19, especially those without severe comorbidities, and he likens it to other respiratory illnesses like the flu or cold. He states that there's unnecessary stigmatization and pressure for vaccination even though it may not be highly effective. Risch argues that what matters in managing a pandemic is the severity of the illness, not just the number of cases.

Vaccine Harms: Dr. Harvey Risch highlights concerns about the side effects and adverse events associated with COVID-19 vaccines. He mentions the increased risk of myocarditis and blood clots, as well as the vaccine's ability to distribute spike proteins throughout the body. Risch questions the initial understanding that the vaccine would stay in the muscle and lymph nodes for immune response and notes that the FOIA documents reveal otherwise. The spike proteins are found in various places in the body, and they may lead to clotting problems, inflammatory issues like myocarditis, neurological problems, and potential fertility issues. While these concerns are not scientifically strong, they raise the possibility of adverse effects from the vaccines, which he believes require further study over the next five to ten years to ensure the public health approach is just.

Dr. Harvey Risch - Senate Hearing (Jan 24, 2022)

WATCH VIDEO

Dr. Risch discusses the effectiveness of hydroxychloroquine and ivermectin in early outpatient COVID-19 treatment, citing extensive studies involving over 40,000 patients, showing significant reduction in hospitalization and mortality risk with these medications. He criticized the media's portrayal of these alternatives, and the FDA for issuing a fraudulent warning against hydroxychloroquine use. He discussed the unlikelihood of a more pathogenic variant emerging from oomicron and raised concerns about the impact of booster shots on natural immunity, citing data showing potential immune response damage from vaccines. Dr. Risch cites public health data which indicates that individuals who had COVID-19 and then received vaccinations had lower levels of specific antibodies, suggesting potential damage to the immune response from the vaccines.

Dr. Harvey Risch: mRNA Adverse Reaction Data Suppressed by CDC WATCH VIDEO

Doubts About the Validity of Studies: Dr. Risch details concerns about the validity of studies, particularly in the context of the COVID-19 pandemic. The studies mentioned are questioned for their design, accuracy, and potential conflicts of interest in the pharmaceutical industry. He emphasizes that much of what has been presented to the public as scientific knowledge during the pandemic has been based on plausible theories rather than concrete scientific evidence.

Challenges with Randomized Controlled Trials: Randomized controlled trials (RCTs) are often considered the gold standard in medical research. However, Dr. Risch explains that randomization may not work effectively with small sample sizes, which leads to bias and confounding factors that affect the study's outcomes. He provides an example of the Pfizer vaccine trial with a small number of events in the treatment group, rendering the randomization ineffective.

Pharmaceutical Industry Influence: Dr. Risch details how conflicts of interest in medical research are a major problem, and how pharmaceutical companies have a playbook for influencing research outcomes, including underpowered studies, failure to disclose conflicts of interest, and disparaging experts who criticize studies. He explains that this influence extends to studies published in prestigious medical journals. He references the establishment of the ClinicalTrials.gov database to address some of these problems but notes that manipulation and flawed study design continue to be significant challenges.

Effective Outpatient Treatments: Dr. Risch emphasizes that there have always been effective treatments for COVID-19 when used early. He mentions a combination of medications, including hydroxychloroquine, ivermectin, budesonide, corticosteroids, vitamin D, and zinc, that have shown effectiveness in treating COVID-19 in outpatients when administered within the first 4-5 days of symptoms. Dr. Risch points out how the FDA and CDC actively suppressed these effective outpatient treatments for COVID-19, even though they are extremely safe, as they have been FDA-approved for human use for decades.

Concerns about Spike Protein Shedding: The interview touches on concerns about shedding spike proteins from vaccinated individuals. The interviewer and Dr. Risch debate how spike proteins could be transmitted between individuals and are uncertain about the implications. They also raise concerns about the safety and security of the blood supply, especially when blood from vaccinated individuals may contain circulating spike proteins.

Data analysis: Dr. Risch discusses the app V-Safe, which was downloaded by 10 million people, and the alarming revelation that 800,000 of these individuals had to go to the hospital due to vaccine-related adverse events. Specifically, around 13% of the app users reported being too unwell to work after their first vaccine dose, while 8% ended up in the hospital due to these events. This data raises concerns about the safety of COVID-19 vaccines, detailing a significant number of adverse reactions. These findings are a warning against vaccine mandates, with a particular focus on the vaccines' inability to effectively prevent virus transmission, which, according to the Jacobsen v. Massachusetts case criteria, raises constitutional questions about the mandates' validity. Dr. Risch strongly opposes vaccine mandates, and mentions how these mandates led to a significant loss of healthcare professionals.

Immune system and current respiratory illnesses: The discussion touches upon the potential impact of reduced exposure to viruses during lockdowns and the immunosuppressive effect of vaccines. Dr. Risch suggests these factors might contribute to an increase in illnesses like RSV. He also mentions that the current situation with respiratory illnesses might not be as dire as some suggest. Dr. Risch discusses the concept of viral interference, suggesting that high levels of interferon from one virus can prevent the contraction of other respiratory illnesses.

Amnesty and the change in media and government behavior: Dr. Risch suggests that in 1976, the media had two sides, and federal agencies were more circumspect about their actions due to the risk of criticism. In contrast, the current situation reflects a closer relationship between media, pharmaceutical companies, and government agencies. Dr. Risch argues that this close relationship has led to more brazen actions by federal agencies without fear of criticism. Dr. Risch expresses skepticism about granting amnesty to individuals who made decisions that led to negative consequences during the COVID-19 pandemic. He argues that those who intentionally misled the public should be held accountable, especially if they haven't apologized for their actions.

Epidemiologist Dr. Harvey Risch On Vaccine-Induced "Turbo-Cancers"

WATCH VIDEO

Strange Cancers after Vaccination: Dr. Risch discusses reports of unusual and aggressive cancers occurring in some individuals who have been vaccinated against COVID-19. He clarifies that he did not say billions of people would get cancer, but rather noted that the cancers that have appeared have been notably aggressive.

Mechanism of Cancers: Dr. Risch explains that the immune system plays a crucial role in detecting and eliminating abnormal or cancerous cells. When cancers develop, they present different markers on their surface, which should trigger the immune system to recognize and destroy them. However, damage to the immune system could lead to cancers growing more rapidly.

Immune System Damage: Dr. Risch suggests that vaccines may be damaging the immune system, making it less effective at detecting and combating abnormal cells, which could be contributing to the observed aggressive cancers. He also mentions that vaccinated individuals are getting COVID more frequently than unvaccinated individuals once the vaccine's protective effects wane.

Turbo Cancers: The term "turbo cancers" is used to describe these exceptionally fast-growing and aggressive cancers. Dr. Risch emphasizes that such cancers can be harder to treat due to their rapid growth. He explains that rapidly growing cancers are being diagnosed at younger ages and in advanced stages. This is unusual for certain types of cancer, like colon cancer, and may indicate a connection to immune system damage caused by the vaccines.

Talc Contamination: The discussion touches on potential contaminants in vaccines. Dr. Risch points out that contamination with substances like SV40, a known carcinogen, could be a risk, and this contamination may be related to manufacturing processes.

Prevention and Monitoring: Dr. Risch highlights the importance of cancer prevention and suggests that monitoring cancer cases and their association with vaccines will be crucial. He also mentions a product that may help reduce spike protein levels in the body and its potential role in preventing certain post-vaccination complications.

FDA Oversight and Cover-Up: Dr. Risch comments on the need for stricter quality control and oversight in vaccine manufacturing to prevent contamination and potential risks. The interview touches on claims that the FDA's and other agencies' lack of transparency about vaccine risks, including heart and clotting issues.

Dr. Harvey Risch Presentation on COVID Vaccine Effectiveness at the European Parliament (May 3, 2023)

WATCH VIDEO

Decline in Vaccine Efficacy Over Time: Dr. Risch presents data from studies on the Moderna and Pfizer vaccines, notes that vaccine efficacy decreases and, in some cases, goes below zero. He points out that this decline in efficacy raises concerns about the long-term effectiveness of these vaccines.

Increased Risk with Additional Doses: Dr. Risch also mentions that vaccine efficacy diminishes as more doses or boosters are administered. He points to data from a study in Qatar showing that after four to six months, the efficacy of the vaccines becomes negative. This implies that vaccinated individuals may be more likely to get infected with COVID-19 than those who have never been vaccinated.

CDC Statement on Vaccine Ineffectiveness: Dr. Risch highlights a statement by the CDC, where they assert that the vaccines do not work for the purposes of public health infection control. The statement specifies that vaccines provide minimal protection against infection and transmission, and this protection may wane over time.

Methodological Flaws in Vaccine Efficacy Studies: Dr. Risch criticizes the CDC's methodology for assessing vaccine efficacy, particularly in publications. He points out that the CDC erroneously uses case-control study methods, which are not appropriate for estimating vaccine efficacy. This flawed methodology leads to an overestimation of vaccine efficacy. Dr. Risch specifically mentions that the CDC's approach misrepresents the actual vaccine efficacy and expresses skepticism about the agency's credibility.

Robert Malone, MD

Website
Wikipedia

- Dr. Malone received his M.S. in Medical Science from Northwestern University Medical School in 1984 and his M.D. from Northwestern University Medical School in 1985.
- He completed his residency in surgery at the University of California, Davis, and later pursued a fellowship in pediatric surgery at UC Davis. He also conducted research in the field of mRNA biology.
- Dr. Malone was involved in mRNA vaccine technology research, and worked on the development of in vitro transcription of RNA and its applications. This research laid the groundwork for the development of mRNA-based vaccines, including those for COVID-19 such as Pfizer-BioNTech and Moderna.
- He has been an entrepreneur in the biotechnology and pharmaceutical industries, and co-founded Atheric Pharmaceutical, a company focused on developing treatments for rare diseases.
- Dr. Malone served as a consultant and advisor to various biotech and pharmaceutical companies and organizations, contributing to discussions on mRNA technology and vaccines.
- Dr. Malone has authored or co-authored numerous scientific publications, and holds numerous patents related to mRNA vaccine technology. He has been involved in advocacy efforts to promote mRNA vaccine technology and has been a public figure in discussions related to vaccine development and the COVID-19 pandemic.

Dr. Robert Malone: New COVID Vaccine Data May Open The Window For Long-Term Side Effects "Way Up!"

WATCH VIDEO

Dr. Robert Malone discusses critical information about the lipid nanoparticles used in mRNA vaccines, specifically focusing on how they differ from the spike proteins created by the vaccines. He highlights that the lipid nanoplex is inherently inflammatory, distinguishing it from the spike proteins. The mRNA delivered in these vaccines is not traditional mRNA but a highly modified molecule they call "m-mRNA." Contrary to earlier claims that it degrades within a few hours, it is revealed that this molecule is far more stable and contains pseudouridine, a natural molecule that modifies RNA function. However, the modification renders it immunosuppressive, which was an intentional design choice to mitigate inflammation. This immunosuppressive quality can affect not only the inflammatory response but also other immune responses, potentially leading to unforeseen consequences.

Moreover, Dr. Malone points out that these highly modified m-mRNA molecules have an extended half-life, challenging the belief that they dissipate quickly. This discovery has significant implications as it suggests the possibility of spike protein production continuing long after vaccination, which challenges the timeline within which adverse events are typically assessed. He emphasizes that the current data on adverse events and deaths linked to vaccines may be flawed due to this extended window of spike protein production, which warrants a reevaluation of vaccine-related safety data.

Highlights of Dr. Robert Malone's 3-Hour Interview on Joe Rogan

WATCH VIDEO

Dr. Robert Malone and Joe Rogan cover a multitude of critical issues related to COVID-19, vaccines, and public health. They explore the claim of a 500,000 COVID-19 death toll in the U.S., due to the intentional obstruction of early treatment options.

Dr. Malone reveals the role of individuals like Janet Woodcock and Rick Bright in restricting the use of Hydroxychloroquine. Moreover, he discusses a decision made in a meeting between President Joe Biden and India's Prime Minister Modi, withholding effective COVID-19 treatments in India.

The conversation delves into vaccine safety, highlighting potential risks for individuals who have previously had COVID-19 and how media outlets label informed critiques as "anti-vaxxer misinformation."

Dr. Malone questions the effectiveness of COVID-19 lockdowns and explores Israel's strict vaccination measures, suggesting they may not be achieving the expected results.

The discussion examines potential financial incentives for hospitals to promote the COVID-19 and Great Reset narrative and reveals financial connections between media outlets and pharmaceutical companies.

Dr. Robert Malone Describes Growing List Of Illnesses Associated With Dangerous COVID Vaccines

WATCH VIDEO

Dr. Malone discusses several concerning aspects of COVID-19 vaccines. He suggests that the data indicates that vaccination may not be as effective as initially thought, potentially increasing the risk of infection, hospitalization, and death compared to the unvaccinated.

Moreover, he delves into adverse events associated with the vaccines, particularly myocarditis, which may be linked to the reactivation of latent DNA viruses, including Epstein-Barr virus and others. These viruses, normally kept in check by T-cell function, may be unleashed by the vaccines, contributing to post-vaccination symptoms like low energy and general malaise.

Dr. Malone raises concerns that taking additional vaccine doses, especially when they don't guarantee protection against infection, might increase the likelihood of getting infected. He highlights that vaccine-related issues extend beyond COVID-19 to include potential T-cell suppression, reactivation of latent DNA viruses, a potential increased risk of cancers, and blood clotting problems that can impact various organs.

His discussion underscores the importance of understanding the full spectrum of potential vaccine side effects, including the broad impact of blood clotting issues on multiple organs, and the significance of these considerations for public health.

Dr. Malone Warns Parents About Vaccinating Children Against COVID

WATCH VIDEO

Dr. Robert Malone, a physician, scientist, father, and grandfather, addresses the crucial topic of COVID-19 vaccination for children. While he emphasizes his pro-vaccination stance, he raises important concerns about the genetic vaccines being used. Key points he makes:

Genetic Vaccines: He highlights that these vaccines inject viral genes into children's cells, compelling their bodies to produce potentially harmful spike proteins. These proteins can cause permanent damage to critical organs, including the brain, heart, blood vessels, and reproductive system. Additionally, the vaccine can lead to fundamental changes in the child's immune system, with all these damages being irreversible.

Limited Testing: Dr. Malone points out that this novel technology has not undergone sufficient testing and research. He stresses the need for at least five years of research to comprehend the full extent of the risks associated with this approach.

Immunity from COVID: He challenges the idea that vaccinating children is necessary, arguing that their natural immunity after contracting COVID is crucial for family and global protection.

In conclusion, Dr. Malone contends that the known health risks of the vaccine outweigh the potential benefits, and he urges parents to resist and fight for their children's well-being. He suggests that the risk-benefit analysis for vaccinating children with this vaccine is not in their favor and calls for thoughtful consideration of these concerns.

Peter McCullough, MD

Website
Wikipedia

- Dr. McCullough earned his medical degree (MD) from the University of Texas Southwestern Medical Center, one of the leading medical schools in the United States.
- He earned a Master of Public Health (MPH) degree from the University of Michigan, demonstrating an interest in public health and epidemiology.
- Recognized Fellow of the American College of Cardiology (FACC), and recognized Fellow of the Heart Failure Society of America (FHFSA), both prestigious designations among cardiologists.
- Dr. McCullough served as the Chief of Cardiology at Baylor University Medical Center, and is currently a Professor of Medicine at Texas A&M University College of Medicine, actively involved in teaching and research.
- Dr. McCullough holds the role of Editor-in-Chief for the medical journal "Reviews in Cardiovascular Medicine."
- Dr. McCullough is a prolific researcher and has authored or co-authored numerous peer-reviewed articles, book chapters, and abstracts in the field of cardiology and internal medicine. He has made notable contributions to topics such as heart disease, hypertension, and kidney disease.
- Dr. McCullough contributed to the development of clinical guidelines and consensus statements related to various medical conditions, particularly in the field of cardiology.
- Dr. McCullough is a practicing cardiologist and internist with extensive clinical experience. He has a long history of providing medical care to patients with cardiovascular diseases and internal medicine conditions.

Peter McCullough at the European Parliament (September 14, 2023)

WATCH VIDEO

Two Waves of Injury: Dr. McCullough details two waves of injury during the COVID-19 pandemic. Firstly, the SARS-CoV-2 infection that affected the frail and elderly. Secondly, the COVID-19 vaccines, the focus of this speech.

Origins of SARS-CoV-2: Dr. McCullough explains that the investigation by the WHO into the origins of SARS-CoV-2 was compromised and that the engineered nature of the virus in a US-Chinese collaboration was suppressed.

Adverse Effects of COVID-19 Vaccines: Dr. McCullough highlights that vaccines, particularly mRNA vaccines, contain genetic code for the spike protein of the virus, and that installing this genetic code in the human body is problematic.

Domains of Vaccine-Induced Harm: He outlines four major domains of harm caused by COVID-19 vaccines: cardiovascular disease, neurologic disease, blood clots, and immunologic abnormalities. He provides examples of conditions within each domain, such as myocarditis, stroke, blood clots, and inflammatory disorders.

Calls for Vaccine Removal: He mentions that various organizations and expert panels have called for the removal of all COVID-19 vaccines from the market due to safety concerns. Dr. McCullough implores the European Medicines Agency (EMA) to apply pressure to remove the vaccines from the market.

Implication for the W.H.O.: Dr. McCullough expresses his belief that the European Union and other major stakeholders should consider distancing themselves from the WHO and its jurisdiction over healthcare decisions, suggesting that the WHO has supported vaccines that are more problematic than helpful.

COVID & Dangerous Vaccine Policy | Peter McCullough, Bret Weinstein

WATCH VIDEO

Peter McCullough raises concerns about COVID-19 and vaccine policy. According to McCullough, vaccination must be approached with caution and a focus on risk stratification, as blood clotting is a common complication of COVID-19 and the incidence of returning cases is much lower than the CDC has stated. He suggests that teams of qualified doctors should have been working on reducing the spread of the illness, early treatment, hospital treatment, and vaccination, and that there should have been a data safety monitoring board, critical event committee, and human ethics board for vaccines to ensure safety and efficacy. McCullough questions the safety of current COVID vaccines, citing the lack of long-term clinical trial data, and potential harm to vulnerable groups. Weinstein expresses concerns about the potential for government overreach and the use of mandates to force people to get vaccinated, arguing that such measures are not scientifically grounded and risk infringing on individual freedoms. The pharmaceutical industry also plays a role in shaping public health policy, with profit motives prioritized over safety and efficacy.

Peter McCullough, MD testifies to Texas Senate HHS Committee

WATCH VIDEO

Dr. Peter McCullough testifies to the Texas Senate HHS Committee about the lack of attention given to treating COVID-19 patients. He emphasizes the importance of early ambulatory treatment and highlights his own research on the subject. Dr. McCullough criticizes the lack of information provided to the public about treatment options and the failure of medical societies and government agencies to prioritize treatment efforts. He advocates for the implementation of treatment guides, hotlines, and research initiatives to prevent hospitalizations and deaths. Dr. McCullough also expresses frustration with the dismissal of certain drugs and the lack of compassion and care towards COVID-19 patients.

Dr Peter McCullough on The Joe Rogan Podcast (Excerpt)

WATCH VIDEO

Dr. Peter McCullough discusses his testimony in U.S. and Texas Senate regarding early treatment for COVID-19. He believes that establishment of his protocol distributed worldwide could have reduced COVID-19 death significantly. Studies carried out in Dallas Fort Worth showed early multi-drug therapy works with outpatient. He also believes there was intentional suppression of early treatment to create fear and promote mass vaccination. Dr. McCullough mentions several books --- Covid 19 in The Global Predators, We Are the Prey, and The Real Anthony Fauci --- which provide evidence of a conspiracy between various organizations in the development of the COVID-19 vaccine, and operations between these organizations.

Dr. McCullough Raises Three Alarming Concerns About COVID Vaccines

WATCH VIDEO

1. **COVID vaccine contents undisclosed:** Manufacturers like Pfizer, Moderna, and Johnson & Johnson have not fully disclosed the ingredients in their vaccines, raising questions about transparency.
2. **Widespread distribution of lipid nanoparticles:** Lipid nanoparticles in COVID vaccines can travel throughout the body, potentially reaching the brain, heart, reproductive organs, and more. The spike proteins contained in the vaccines are known to be toxic and can harm the body. Furthermore, the vaccines compel the body to generate these harmful proteins.
3. **Genetic code alteration:** The genetic code of the vaccines can enter the nucleus of human cells and modify our DNA. This raises concerns about permanent genetic changes, with implications for long-term health and potential chronic illnesses.

Dr. McCullough on Mass Loss of Life, CDC Failures and False Claims

WATCH VIDEO

Dr. Peter McCullough discusses recent changes in the CDC's stance on COVID-19 vaccines and the impact on individuals, vaccine mandates, and ongoing concerns about vaccine safety. He highlights the CDC's shifting positions on vaccine effectiveness and the false claims made regarding the vaccines' ability to prevent infection, transmission, and severe disease. Dr. McCullough also raises concerns about the long-term effects of the vaccines, including the presence of genetic material in lymph nodes and spike proteins in the body, which he suggests may be associated with side effects.

He calls for reforms at the CDC, including changes in leadership, external oversight, and accountability. Dr. McCullough questions the need for vaccine mandates and emphasizes the importance of individual health, as well as the potential risks and safety issues associated with the COVID-19 vaccines. The interview also touches on the financial interests and profit motives of pharmaceutical companies in the vaccine distribution and approval process.

Dr. McCullough's viewpoints are critical of the CDC, FDA, and the pharmaceutical industry's handling of COVID-19 vaccines and emphasize the need for transparency and accountability in public health policies and decisions.

Michael Yeadon, Ph.D.

Website
Life Sciences EU
Wikipedia

- Michael Yeadon is a British scientist with a background in pharmacology and extensive experience in the pharmaceutical industry.
- Yeadon holds a Ph.D. in respiratory pharmacology from the University of Surrey, Guildford, United Kingdom.
- He has held various academic positions, including being an Honorary Research Fellow at the University of Surrey, where he conducted research in the field of respiratory pharmacology.
- Yeadon served as the Vice President and Chief Scientific Officer for Allergy and Respiratory at Pfizer, and has 30 years of experience in the pharmaceutical industry, with extensive background in drug discovery and development, particularly in the fields of allergy and respiratory medicine.
- Yeadon has authored or co-authored numerous research papers in the fields of respiratory pharmacology and related areas. His work has contributed to scientific knowledge in these domains.
- He is known for his expertise in pharmacology, drug development, and respiratory diseases, particularly asthma and allergies. This expertise is based on his academic background and extensive experience in the pharmaceutical industry.

Dr. Michael Yeadon Examines Pandemic Measures and Vaccine Safety

WATCH VIDEO

Dr. Michael Yeadon discusses several key points related to vaccine safety, adverse reactions, media manipulation of information, and unnecessary COVID-19 protocols.

PCR Test and Misrepresentation of the Pandemic: Dr. Michael Yeadon highlights the unreliability of PCR testing due to high cycle thresholds, potential contamination issues, and the lack of negative controls, which he suggests have led to an overestimation of COVID-19 cases.

Immunity and Vaccination: Dr. Yeadon questions the necessity of vaccines, particularly mRNA-based vaccines, and suggests that they may not be effective or safe. He highlights the importance of natural immunity and suggests that mass vaccination is not justified.

Adverse Reactions: Dr. Yeadon mentions reports of individuals experiencing severe adverse reactions or even dying shortly after receiving the COVID-19 vaccine. He suggests that these adverse events are more concerning than the virus itself, especially in young and healthy individuals.

PCR Test and Asymptomatic Transmission: The discussion also touches on the idea of asymptomatic transmission, with Dr. Yeadon disputing the notion that asymptomatic individuals are significant sources of infection. He points out that people who are truly infectious will likely exhibit symptoms.

Overall, Dr. Yeadon expresses skepticism about the prevailing narrative related to the pandemic and the public health measures taken. He raises concerns about the safety and efficacy of COVID-19 vaccines and suggests that natural immunity and alternative treatments should be considered.

Dr. Yeadon's Warning: COVID Vaccine Safety and Pregnancy

WATCH VIDEO

In this talk by Dr. Michael Yeadon, the focus is on the safety of COVID-19 vaccines, particularly in relation to pregnancy. Dr. Yeadon expresses deep concern about the lack of comprehensive studies characterizing the safety of these vaccines. He highlights the complexity and experimental nature of these medicines and emphasizes that no assumptions can be made about their safety during pregnancy. He draws a parallel with the tragic history of thalidomide, which caused severe birth defects, and strongly criticizes physicians who administer the vaccine to pregnant women, calling them "reckless idiots." He advises women who may be pregnant or planning to become pregnant to avoid the vaccine. Dr. Yeadon's message underscores the need for rigorous safety assessments, especially in vulnerable populations like pregnant women.

Data-Driven Conversation with Dr. Michael Yeadon On Vaccine Safety

WATCH VIDEO

Dr. Michael Yeadon expresses serious concerns about the safety and necessity of COVID-19 vaccines, particularly for adolescents and children. His key points include:

Safety Concerns: Dr. Yeadon argues that COVID-19 vaccines are not safe due to their gene-based design, which makes the body produce the virus spike protein, known to trigger blood clots. He claims that approximately 75% of adverse events after vaccination are related to blood clots and bleeding.

Lack of Necessity for Younger Age Groups: Dr. Yeadon emphasizes that young people, especially those under 70 and without underlying health issues, are not at significant risk from COVID-19. He suggests that the risk of vaccination may outweigh the risk of the virus itself, making vaccination for this demographic unnecessary.

Statistical Data: He references the increasing number of serious adverse events reported after COVID-19 vaccinations, particularly deaths, and highlights that these figures far exceed typical vaccine-related deaths. He cites this data as evidence that the vaccines may not be as safe as they are portrayed.

Where to Find Information: Dr. Yeadon recommends the American Association of Physicians and Surgeons' website for more information and points to Dr. Peter McCulloch, a noted cardiorenal specialist, as a source of valuable guidelines and information.

Dr. Yeadon Explains How COVID Vaccine Causes Autoimmune Disorder

WATCH VIDEO

Dr. Michael Yeadon raises several concerning points about the COVID-19 vaccines:

L**ack of Testing in Pregnant Women:** Dr. Yeadon emphasizes that experimental medicines are never given to pregnant women due to the potential risks they pose to both the mother and the developing fetus. He expresses deep concern over governments urging pregnant women and women of childbearing age to get vaccinated when proper reproductive toxicology tests haven't been conducted.

Vaccine Distribution in Ovaries: He brings attention to a study from the Japanese medicines regulator, revealing that the vaccine concentrates in the ovaries of rats, raising questions about its safety in human ovaries. This phenomenon is not well understood, and the implications could be far-reaching, given that the vaccine expresses the coronavirus spike protein.

Autoimmune Response: Dr. Yeadon also discusses a study involving 15 women who received the Pfizer vaccine. The study found that these women developed a significant increase in antibodies against their own placenta, which plays a crucial role in fertilization and successful pregnancy. This suggests a vaccine-induced autoimmune attack on the placenta, raising concerns about the impact on fertility and pregnancies in women who receive the vaccine.

Rand Paul, MD, US Senator

Website
Wikipedia

- Rand Paul is a U.S. Senator from Kentucky, elected to the Senate in 2010. and reelected to serve multiple terms.
- Rand Paul received his undergraduate degree in Biology from Baylor University, and earned his Doctor of Medicine degree from Duke University's School of Medicine.
- Before entering politics, Rand Paul had a successful practice as an ophthalmologist, and was board-certified by the American Board of Ophthalmology.
- Rand Paul founded and operated the Southern Kentucky Lions Eye Clinic, a non-profit organization that provided eye care and surgery to low-income individuals in Kentucky.
- Senator Paul has been a member of various Senate committees, including the Committee on Foreign Relations, Committee on Homeland Security and Government Affairs, Committee on Health, Education, Labor, and Pensions, and the Committee on Small Business and Entrepreneurship.
- Rand Paul authored and co-authored multiple peer-reviewed medical papers, contributing to the field of ophthalmology.
- He was associated with professional medical organizations like the American Board of Ophthalmology and the American Academy of Ophthalmology.

U.S. Senator Rand Paul Speaks Against COVID-19 Vaccine Mandates

WATCH VIDEO

Senator Rand Paul questions the Senate's COVID-19 booster mandate for Senate pages, highlighting the disparity in treatment compared to the military. He argues that there's no scientific basis for the mandate, especially for healthy children who face low COVID-19 risks. Senator Paul cites studies and experts to back his claims and underscores the potential risks of boosters, particularly heart inflammation. He calls for ending the mandate and a reevaluation of vaccine mandates for young, low-risk individuals.

Reports of Myocarditis: Senator Paul points out that there have been consistent reports of heart inflammation, particularly myocarditis, occurring after COVID-19 vaccination. He emphasizes the significance of this adverse effect.

Increased Risk After the Second Dose: The senator highlights that approximately 90% of cases of myocarditis occur after the second COVID-19 vaccine dose, indicating an elevated risk associated with subsequent doses.

Comparative Risk: Senator Paul emphasizes the need to consider the comparative risks of COVID-19 vaccination and the disease itself, particularly among young, healthy individuals. He argues that the risk of myocarditis from the vaccine may outweigh the risk of hospitalization due to COVID-19.

Various Studies Confirming Myocarditis Risk: He refers to studies, including one published in the Journal of the American Medical Association Cardiology and another in the Journal of Medical Ethics, that found an increased risk of myocarditis after COVID-19 vaccination.

Challenging Vaccine Effectiveness: Senator Paul suggests that, beyond the potential risks of vaccine injuries, there is doubt regarding the effectiveness of COVID-19 vaccines in preventing transmission and severe illness. He argues that the benefits of vaccines for young, healthy individuals might be minimal or nonexistent.

Dr. Rand Paul Interview on The National Desk

WATCH VIDEO

Senator Rand Paul confronts Dr. Fauci, challenging him on the topic of natural immunity and vaccine efficacy. Paul calls out Fauci on his previous statements, particularly his claim that enduring the flu could offer better immunity than vaccination, and that contracting the virus is the superior route to immunity. Fauci, however, weaves through the argument, alleging that these statements were misconstrued and related to vaccine reactions. Paul accuses Fauci of sidestepping fundamental principles of immunology and disregarding the truth. The debate escalates as they dissect the roles of FDA and CDC advisory committees in vaccine approval. Fauci deflects, stating that he is not responsible for these decisions and professes ignorance regarding royalties and conflicts of interest within these committees. This contentious exchange highlights Fauci's agility in manipulating his argument to avoid overt contradictions while his stance on natural immunity continues to evolve.

Dr. Rand Paul Interview on The National Desk

WATCH VIDEO

COVID-19 Pandemic: Senator Paul highlights that COVID-19 is not likely to disappear entirely and compares it to other coronaviruses that have been present in society for many years. He emphasizes that most Americans now have some form of immunity, either from vaccination or previous infection. He raises concerns about pushing for additional vaccines, particularly for children, without considering the immunity acquired through prior infection.

Investigation into COVID-19 Origins: Senator Paul advocates for a thorough investigation into the origins of COVID-19, especially if it is found to have been associated with a lab involved in gain-of-function research. He believes that such research needs to be tightly regulated and treated with the same level of scrutiny as other dangerous technologies.

Response to Inflation: Senator Paul attributes the current high inflation to the lockdowns implemented during the COVID-19 pandemic. He explains that the injection of free money into the economy increased the money supply, resulting in inflation. He argues that lockdowns should not be repeated because they have adverse economic consequences.

Rand Paul Tells Fauci He Changed Website To 'Cover Your Ass' On Gain-Of-Function Research

WATCH VIDEO

Senator Rand Paul questions Dr. Anthony Fauci about the funding of gain-of-function research in Wuhan. Senator Paul accuses Dr. Fauci of repeatedly denying his involvement in approving funding for this type of research. He argues that the NIH funded experiments that created viruses not found in nature and that gained in lethality. According to Senator Paul, gain-of-function research with laboratory-created viruses could lead to worse pandemics in the future.

Dr. Fauci defends his position, stating that the definition of gain-of-function research is a matter of debate and has been redefined over time and argues that the research conducted in Wuhan did not meet the current definition of gain-of-function.

Senator Paul accuses Dr. Fauci of misleading the public and supporting research in Wuhan, even though the preponderance of evidence suggests that the pandemic originated from a lab leak. He criticizes Dr. Fauci for changing the definition of gain-of-function on the NIH website to avoid acknowledging the riskiness of the research. Senator Paul calls for Dr. Fauci's resignation due to his lack of judgment in handling the situation.

Dr. Fauci refutes Senator Paul's claims, stating that he has no responsibility for the current pandemic. He also disagrees with the notion that the lab leak theory is more likely than a natural occurrence. Dr. Fauci emphasizes that the overwhelming scientific consensus does not support the lab leak theory.

Sen. Rand Paul Confronts Moderna CEO About the Risk of Myocarditis in Young Males

WATCH VIDEO

Senator Rand Paul questions Moderna CEO Stéphane Bancel regarding financial transactions between Moderna and the NIH and the potential conflict of interest arising from government employees benefiting from vaccine-related decisions. The interview also delves into the safety concerns surrounding the Moderna vaccine, specifically focusing on myocarditis risk in adolescent males. Senator Paul challenges the idea of mandating vaccines for this demographic and discusses varying international approaches to COVID-19 vaccination for children. Throughout the interview, concerns about potential financial conflicts of interest are addressed, and the CEO's public and private statements regarding vaccine risks are scrutinized.

Senator Rand Paul raised concerns about the risk of myocarditis associated with COVID-19 vaccines, referencing six peer-reviewed papers from the Journal of Vaccine and the Annals of Medicine that suggested an increased risk in adolescents, particularly after the second vaccine dose.

Bancel's statements regarding the safety of Moderna's vaccine, particularly in relation to myocarditis in young individuals, were countered by Senator Rand Paul, who substantiated his assertions with research and peer-reviewed papers, revealing the inadequacy of Bancel's arguments.

Kary Mullis, Ph.D.

Website
Nobel Prize
Wikipedia

- Bachelor of Science (B.S.) in Chemistry from Georgia Institute of Technology in 1966.
- Ph.D. in Biochemistry from the University of California, Berkeley in 1972.
- Postdoctoral fellowship at the University of Kansas Medical Center. Also, a postdoctoral researcher at the University of California, San Francisco, and later as a research scientist at the Cetus Corporation.
- **Invention of PCR:** Dr. Mullis is most renowned for his invention of the Polymerase Chain Reaction (PCR) in 1983, a groundbreaking technique in molecular biology that revolutionized DNA analysis and replication.
- Nobel Prize in Chemistry in 1993 for his development of the PCR technique, shared with Michael Smith.
- California Scientist of the Year in 1990.
- Dr. Mullis authored numerous scientific papers and articles, primarily related to PCR and DNA amplification techniques.
- Member of the National Academy of Sciences.

Dr. Kary Mullis on Anthony Fauci (Gary Null Interview Excerpt, 1996)

WATCH VIDEO

Dr. Kary Mullis expresses skepticism about certain individuals' qualifications in the fields of science and medicine, particularly referring to Dr. Anthony Fauci. He questions their understanding of scientific concepts, such as electron microscopy and medicine, and suggests they lack the necessary expertise for their positions in public health administration. Dr. Mullis also mentions concerns about personal agendas and rule-changing among those in authoritative roles. He believes that many people lack the ability to judge who is a good scientist and highlights a significant issue in this century: science being evaluated and funded by individuals who may not fully comprehend it, such as Dr. Fauci. Dr. Mullis suggests that Dr. Fauci should engage in debate with someone with a different perspective to provide a more balanced discussion on the subject, but notes Dr. Fauci declined such an opportunity.

Kary Mullis Speaks Out Against the Misinterpretation of the PCR Test

WATCH VIDEO

Dr. Kary Mullis addresses the misinterpretation of PCR (Polymerase Chain Reaction) results. He argues that PCR itself is a precise and quantitative tool that can detect a wide range of molecules in a sample, even in minuscule quantities, but emphasizes that some people misconstrue the extensive detection capabilities of PCR.

Mullis explains that PCR's sensitive detection capabilities can lead to the misinterpretation that various molecules and elements are somehow linked or present in association with one another in a sample. This misinterpretation occurs when people assume that, because PCR can amplify and detect a wide range of molecules, it implies a broader, more interconnected relationship between these molecules than what actually exists. Mullis is cautioning against drawing unwarranted conclusions from PCR results and emphasizes the importance of accurate interpretation to avoid overinterpretation or misjudgment of the data.

> *"You can amplify one single molecule up to something that you can really measure, which PCR can do. And there's just very few molecules that you don't have, at least a single one of them and your body. So that could be thought of as a misuse of [PCR], just to to claim that it's meaningful".*

Mullis highlights the importance of correctly understanding and interpreting PCR results to avoid misusing the technology in a broader context, especially in virology and disease testing.

Dr. Kary Mullis on the Scientific-Industrial Establishment

WATCH VIDEO

Evolution of Scientific Priorities: Dr. Mullis outlines the transformation in the scientific community's priorities over time. He suggests that after World War II, governments recognized the significance of scientists in influencing military power and the economy, which led to the emergence of the scientific-industrial establishment.

Scientists Driven by Money and Power: He asserts that as financial opportunities became available, scientists increasingly pursued their careers for monetary gain and power. This led to a shift from being driven by curiosity to financial incentives and status.

Misinterpretation of Data in Global Warming: Dr. Mullis presents a skeptical view of global warming and criticizes how data is being misinterpreted. He highlights recent studies that challenge traditional models of global warming, suggesting that the predictions made based on these models may be incorrect. He emphasizes the importance of scrutinizing scientific evidence carefully to avoid unnecessary concerns.

The Complexity of the Earth: Dr. Mullis concludes by emphasizing the Earth's complexity and the existence of mechanisms not yet fully understood by science, making it an awe-inspiring and unpredictable entity. He also touches on the importance of addressing real, immediate threats, such as asteroids, rather than focusing on perceived but potentially less critical concerns.

Gary Null Interview of Dr. Kary Mullis (Full Interview, 1996)

WATCH VIDEO

Among others, the following topics were discussed:

PCR Testing and Its Limitations: Mullis, as the inventor of PCR, is well-qualified to discuss its limitations. Mullis acknowledges that PCR is a powerful and revolutionary molecular biology technique used to amplify DNA. He emphasizes its significance in modern molecular biology and genetic research. This serves as a reminder of his own pioneering work in the field. Mullis implies that the overreliance on PCR testing in certain contexts may lead to misdiagnoses.

Testing Cross-Reactivity: Mullis argues that PCR tests, and many other diagnostic tests, can cross-react with various other conditions. This means that the test may indicate a positive result for a different condition or substance that is not necessarily the one being tested for. This cross-reactivity can lead to misdiagnosis.

False Positives and Misinterpretation: Mullis suggests that PCR testing can yield false-positive results if not used and interpreted correctly. He implies that PCR tests are sensitive and can amplify trace amounts of DNA, which might lead to the misinterpretation of results. This is a valid point; PCR is highly sensitive and can detect even tiny amounts of genetic material, but this sensitivity can lead to false positives if contamination or errors occur during the process.

Misuse of PCR in Diagnosing HIV and AIDS: One of Mullis' most contentious claims is his skepticism regarding the use of PCR in diagnosing HIV and AIDS. He argues that the overreliance on PCR testing may lead to misdiagnoses. He believes that PCR tests may not be specific enough to accurately diagnose HIV infection and that other factors, such as lifestyle and behavior, should be considered alongside test results.

PCR's Role in Disease Diagnosis: Mullis questions the reliance on PCR in the diagnosis of viral diseases. He believes that PCR testing alone is not sufficient to confirm the presence of a virus or, specifically, the development of AIDS. He implies that the scientific and medical communities may overemphasize the role of PCR in diagnosing viral diseases.

The Challenge of Challenging Consensus: Mullis points out that challenging the scientific consensus, especially in cases like HIV and AIDS, can be difficult. He suggests that questioning the established norms and widely accepted diagnostic tests is not always well-received within the scientific community. This reflects the challenges faced by those who hold contrarian views.

The Influence of External Factors: He hints at the influence of external factors such as financial incentives, political pressure, and pharmaceutical marketing in shaping the direction of medical research and diagnostic practices. This implies that PCR testing, like other diagnostic tools, might be influenced by forces that prioritize certain outcomes over others.

Luc Montagnier, Ph.D.

Website
Nobel Prize
Wikipedia

- Montagnier earned his Doctor of Medicine degree from the University of Paris in 1960.
- Montagnier also obtained a PhD in science, specifically in virology, which he completed in 1962.
- Luc Montagnier was awarded the Nobel Prize in Physiology or Medicine in 2008, along with Françoise Barré-Sinoussi and Harald zur Hausen, for his discovery of HIV.
- In addition, Montagnier also received the Prince of Asturias Foundation's Award for Scientific and Technical Research, and the Lasker-DeBakey Clinical Medical Research Award, among others.
- Montagnier held various research and leadership positions during his career, including serving as the Director of the Virology Unit at the Pasteur Institute in Paris.
- He was the Co-founder of the World Foundation for AIDS Research and Prevention, and authored or co-authored a large number of scientific papers and publications in virology and related fields.

Luc Montagnier Warns Covid Vaccine May Lead to 'Neurodegenerative Illness'

WATCH VIDEO

Nobel Laureate Luc Montagnier warns about potential long-term side effects of the COVID-19 vaccine. Specifically, he expresses concerns that the vaccine could lead to "neurodegenerative illness" down the line. He is also quoted as being "outraged" about widespread vaccination of children. The interview suggests the vaccine may have epigenetic transgenerational inheritance effects that cause illness in future generations. Some of the proposed mechanisms discussed include effects of the spike protein and messenger RNA technology used in some vaccines. The video aims to inform people about potential mid and long-term impacts that are still unknown due to the newness of the vaccine technology and lack of long-term studies.

Luc Montagnier: “I Refuse to be Vaccinated”

WATCH VIDEO

Luc Montagnier states that the COVID-19 virus was created in a laboratory setting and did not naturally occur in nature. He also explains how vaccine-resistant variants result from vaccinations and the antibodies they produce.

Citing WHO statistics, the interviewer mentions spikes in death rates after vaccination campaigns, with up to 10,000 deaths attributed to COVID-19 vaccination.

According to Montagnier, vaccinating during a pandemic is "unthinkable", and he criticizes the use of vaccine passports, which he deems "shameful" and "scandalous." Montagnier predicts an increase in vaccine-related accidents, including potential long-term effects like cancer, stating that "we are only getting started." He raises concerns about the RNA in vaccines, suggesting that it may replicate and lead to the formation of double-chain RNA structures in cells, with unforeseeable consequences. Lastly, Montagnier states: “I refuse to be vaccinated.”

Luc Montagnier: Covid-19 has a (manufactured) HIV sequence attached to its ribbon

WATCH VIDEO

Luc Montagnier expresses concerns about the origins of the COVID-19 virus and the inclusion of HIV sequences. He explains that the virus has been manipulated with HIV sequences added, noting this is not a natural occurrence and is the work of molecular biologists. Montagnier refrains from making accusations but speculates on a potential purpose, such as developing an HIV vaccine by incorporating small virus sequences into the coronavirus genome. He emphasizes that these genetic alterations could modify antigenic sites, potentially making the virus recognizable as HIV by the immune system. Montagnier highlights the need to investigate the consequences of these genetic modifications for individuals who have contracted COVID-19, particularly in terms of their immune responses.

Dr. Luc Montagnier addresses the Luxembourg Parliament to discuss COVID-19 vaccination (January 14, 2022)

WATCH VIDEO
FULL TRANSCRIPT

Montagnier expresses concerns about the safety of COVID-19 vaccines:

Iatrogenic Medicine: Citing the Hippocratic principle of "primum non nocere" (first, do no harm), Montagnier voices strong opposition to what he refers to as "iatrogenic medicine." He suggests that if medicine results in deaths, it is problematic and should be avoided; and specifically criticizes medical practices that might lead to patient deaths.

Concerns About Vaccines: Montagnier raises concerns about the safety of certain COVID-19 vaccines, describing them as vaccines as "poisons" and argues that they are not genuine vaccines. He explains that the messenger RNA (mRNA) in these vaccines allows for the translation of its message throughout the entire body without control, raising concerns about unpredictability.

Prion Formation: Montagnier introduces the concept of prions (protein aggregates with a specific conformation) and argues that certain COVID-19 vaccines contain a sequence detected by bioinformatics that can transform into prions. He expresses concern about this transformation, suggesting it could lead to unpredictable protein modifications.

Adverse Effects: Montagnier mentions that they are monitoring 21 individuals who have received two doses of the Pfizer vaccine and one who received Moderna, all of which are mRNA vaccines, and the possibility of DNA being the source of the message in the AstraZeneca vaccine. He notes that 21 people have died from Creutzfeldt-Jakob disease, which is caused by prions, and makes a connection between these deaths and the vaccines.

Civilizational Impact: Montagnier emphasizes that these concerns about vaccines go beyond personal health and safety, arguing that these issues could have far-reaching consequences, potentially impacting civilization itself. He urges people to consider the impact on future generations when making decisions related to vaccination.

Conference call: Luc Montagnier, Reiner Fuellmich, Wolfgang Wodarg.

WATCH VIDEO

Vaccine Antibodies and Variants: Skepticism about COVID-19 vaccines' effectiveness against new variants, as vaccine-generated antibodies primarily target original Wuhan virus, and are less effective against evolving strains.

Immune Response and Spike Protein: Participants emphasize the significance of the virus entry route (airways vs. body liquids) and its impact on the immune response. They express worries about vaccine spike protein toxicity, including blood clotting, and the antibodies' effects on various organs, notably the brain.

Timing of Deaths and Infections: A pattern of deaths occurring shortly after vaccination is noted and correlated. The participants explain that mass vaccination campaigns coincide with a peak in deaths, implying a link between the vaccines and negative outcomes.

Corruption and Financial Interests: They explain how financial incentives and interests (including money paid to hospitals, doctors, and politicians) are driving vaccination campaigns, causing a lack of transparency and suppressing critical information.

Vaccination of Children: The decision to vaccinate children is challenged, and participants question its necessity given the low rate of severe illness in young individuals.

Adverse Reactions and Whistleblowers: Participants share reports of serious adverse reactions to the vaccines, including deaths within a few weeks of vaccination; and how mortality rates are higher than officially reported.

Myocarditis and Heart Infections: Young people (particularly men) are experiencing a higher incidence of myocarditis or inflammation of the heart muscle. Though the cause is unclear, a link to the vaccines is raised.

Timeframes and Long-Term Effects: Participants associate mass vaccination with different waves of negative effects, including: immediate effects; variants; and potential long-term consequences such as neurological effects, autoimmune diseases, and transgenerational issues.

Globalization and Supranational Organizations: Debate on the adverse effects of globalization, and excessive influence of supranational organizations (WHO; World Economic Forum) over government choices and public health. They argue that these organizations wield excessive power, prioritize their interests over those of nations/citizens.

John Ioannidis, MD

Website
Wikipedia

- John Ioannidis is a medical doctor, and received his M.D. degree from the University of Athens School of Health Sciences in Athens, Greece.
- Dr. Ioannidis is a Professor of Medicine, Biomedical Data Science, Statistics, Health Research and Policy at Stanford University. He was also the Director of the Stanford Prevention Research Center.
- Former Editor-in-Chief of the European Journal of Clinical Investigation, he is himself a prolific researcher and scientist (known for his work in epidemiology) with numerous publications in peer-reviewed journals.
- Dr. Ioannidis is renowned for his contributions to the field of meta-research, which involves studying the scientific process itself, including research practices, bias, reproducibility, and the reliability of scientific findings.
- Received several awards and honors for his work, including being elected as a member of the American Society for Clinical Investigation and receiving the Chanchlani Global Health Research Award.
- Founder of the Meta-Research Innovation Center at Stanford (METRICS), an organization focused on improving the quality and reliability of scientific research through research on research.
- His work has had a substantial impact on the practice of evidence-based medicine, emphasizing the importance of critical appraisal of research and the consideration of bias and uncertainty in medical decision-making.

John Ioannidis on COVID-19: The Need for Informed Decision-Making and Global Collaboration (April 17th, 2020)

WATCH VIDEO

Dr. John Ioannidis discusses various aspects of the COVID-19 pandemic. He emphasizes the challenges of obtaining reliable data during a new pandemic, citing gaps in information related to the virus's lethality, infection rates, and the effectiveness of containment measures. He pointed out that there are major gaps in understanding key features of the pandemic, including the true case fatality rate, the number of infections, the eventual impact, and the effectiveness of containment measures.

He mentioned that early estimates of the case fatality rate, such as the WHO's initial estimate of 3.4%, were overestimations, and that further data point to a lower infection fatality rate. Dr. Ioannidis questions the initial case fatality rate estimates and suggests that the true infection fatality rate may be lower, particularly among younger individuals. He analyzes the factors contributing to the severity of the outbreak in Italy, including demographics, healthcare capacity, and decision-making related to admitting patients to hospitals.

He expresses concerns about media sensationalism and panic, explaining that exaggerated estimates lead to unwarranted decisions about societal structures and the future. He underscores the importance of obtaining accurate data for informed decision-making and emphasizes the need for unity in addressing the pandemic while avoiding political and financial conflicts.

John Ioannidis presentation on the Imperial College study (excerpt)

WATCH VIDEO

Ioannidis illustrates how disagreeing with the prevailing consensus on the pandemic, even if supported by scientific evidence, was met with skepticism. He explains how, if you disagreed with what 90% of people believed (or those who were vocal; i.e., who shouted the most), you were simply considered wrong.

Ioannidis then presents an Imperial College study, published in the journal Nature, which claimed that lockdowns in Europe during the first wave of the COVID-19 pandemic saved 3,000,000 lives. He also points out that the same Imperial College team had developed an alternate model, which was used in the United States. Ioannidis shows that using this alternative model in Europe yielded extremely different results, indicating that lockdowns had absolutely no benefit according to this model.

He emphasizes that both models were created by the same experts, making it challenging to determine which one should be trusted; and that this inconsistency raises questions about the expertise and the model selection process.

John Ioannidis: a Comprehensive Assessment of COVID-19 Response, Epidemiological and Public Health Insights, and Future Pandemic Policy

WATCH VIDEO

Multiple Disciplines Required: Ioannidis emphasizes that addressing the COVID-19 crisis requires the integration of various disciplines, including epidemiology, pandemic management, mathematical sociology, psychology, psychiatry, data science, statistics, and many others. He points out several issues with the pandemic, such as poor data quality, limitations in modeling, errors in complex models, lack of multidimensional analysis, and the need for expertise in various crucial disciplines.

Groupthink and Bandwagon Effect: Ioannidis criticizes the tendency toward groupthink and the "bandwagon effect" in which public opinion becomes the dominant narrative, even when it contradicts expert consensus. He highlights that dissenting voices were sometimes ignored or even attacked.

Selective Reporting: He mentions the media's tendency to report what makes the biggest impression or gains more visibility, often focusing on sensational or alarming stories rather than providing a balanced view. Furthermore, Ioannidis explains how selective reporting of data emphasizes the most sensational aspects of the pandemic, leading to misinformed decisions.

Infection Fatality Rate (IFR): Ioannidis discusses variation in the infection fatality rate (IFR) and the impact of underlying health conditions; emphasizing that IFR can vary significantly and is not a constant number. He mentions that the IFR varies by age and underlying conditions, and cites data to illustrate an IFR of around 0.15% for Europe and the Americas and higher averages of 0.3% to 0.4%. He also presents data from Austria, indicating that younger individuals have a very low IFR, while the elderly and frail have much higher risks. Ioannidis discusses the importance of risk stratification, highlighting that not all age groups face the same level of risk: older and frailer individuals face significantly higher risks, while younger, healthier individuals face much lower risks.

Excess Deaths from Pandemic Response: Ioannidis criticizes the effectiveness of lockdowns and cites a study that illustrates differing conclusions regarding the impact of lockdowns. He stresses that the effectiveness of measures like lockdowns should be subject to randomized trials. Ioannidis emphasizes the negative impact of school closures on education and the well-being of the student population. Ioannidis highlights the potential for excess deaths resulting from pandemic response measures. They point to factors such as dysfunctional health systems, poverty, mental health issues, and starvation.

Endemicity and the Future of COVID-19: Ioannidis discusses the possibility of COVID-19 becoming endemic. He suggest that with effective protection, SARS-CoV-2 may become less virulent than the common flu and may eventually coexist with other diseases. He concludes by listing various factors that can affect the course of the pandemic, including modifiable risk factors like obesity, and the importance of adequate public health measures.

John Ioannidis: Science, Politics, and Media (A Retrospective Analysis)

WATCH VIDEO

Influence of Politics and Media: Dr. Ioannidis acknowledges underestimating the influence of politics, media, and external powers on science during the pandemic. He expresses surprise at how science was affected by power struggles, ideological differences, and conflicts, which were not typical in scientific debates.

John Ioannidis emphasizes the need to stay calm, focused, peaceful, and committed to one another. He stresses the importance of not viewing the world as a hostile place and instead fostering mutual understanding, belonging, and positive interactions.

The pandemic prompted the implementation of thousands of different measures by various entities, including politicians, public health officials, scientists, and committees. Ioannidis criticizes the effectiveness of most of these measures, and contends they caused substantial damage.

Impact on Children: Ioannidis highlights that, fortunately, children and young people were relatively protected from severe illness and had a low risk of death due to the virus. However, many of the measures taken, such as school closures and social restrictions, created problems for children's education, social development, mental health, and overall well-being. He further expresses concerns about the long-term repercussions of keeping children from normal social experiences and their ability to make sense of the world.

Jay Bhattacharya, Ph.D.

Website
Wikipedia

- Dr. Bhattacharya holds an MD and Ph.D. in epidemiology and economy, and holds a Master of Public Health.
- Dr. Bhattacharya is a Professor of Medicine at Stanford University, affiliated with several departments/centers at Stanford, such as the Center for Primary Care and Outcomes Research and the Stanford Center on Longevity.
- Dr. Bhattacharya has made significant contributions to research in public health, economics, and medicine, particularly in the areas of health policy, infectious diseases, and global health.
- He has served as an advisor to policymakers and government agencies on issues related to public health, healthcare, and pandemic response.
- Dr. Bhattacharya has published numerous research articles in prestigious peer-reviewed journals, further establishing his academic and professional reputation.

▶ A Sober Evaluation of COVID-19 Vaccines | Dr. Jay Bhatt, Dr. Gigi Foster

WATCH VIDEO

Effectiveness of Vaccines: Dr. Bhattacharya explains that the COVID-19 vaccine trials showed efficacy in preventing symptomatic infections for three months. However, the trials did not assess the vaccines' ability to prevent infection or the impact on severe disease and death. He highlights that the vaccines are not very effective at stopping individuals from getting COVID-19 or preventing the transmission of the virus. It's noted that many vaccinated individuals have still contracted COVID-19.

Protection for Vulnerable Populations: Dr. Bhattacharya suggests using the vaccines for focused protection, particularly for older people who may benefit from reduced risk of severe disease and hospitalization. He recommends prioritizing older populations for vaccination.

Vaccine Safety Concerns: Some populations, like young men, have experienced vaccine-induced myocarditis (inflammation of the heart) at higher rates after vaccination. The safety of the vaccines is discussed in the context of potential side effects, especially for specific groups.

Personal Medical Decisions: Dr. Bhattacharya highlights concerns about making medical decisions for individuals based on the perceived social good, raising potential ethical issues. He discourages the use of coercion to force people into taking the vaccine, and emphasizes that individuals should make decisions about getting the vaccine or other health interventions based on what is best for them personally.

Marketization and Pharmaceutical Companies: The interview alludes to potential legal consequences for pharmaceutical companies, explaining that Pfizer's leadership could face jail time or steep fines in the future due to mistakes and adverse effects of vaccines.

Challenges in Reporting Side Effects: The transcript discusses disincentives for reporting vaccine side effects, which limit the transparency and reporting of adverse events related to COVID-19 vaccines.

Impact of Social Influence: Dr. Bhattacharya briefly mentions the influence of networks and social power in shaping the vaccine narrative and reporting of side effects.

▶ Dr. Jay Bhattacharya at the Covid-19 Accountability Hearing

WATCH VIDEO

Dr. Jay Bhattacharya highlights that the federal government was the primary source of misinformation during the pandemic, using propaganda tactics to control information and suppress dissent. He cites studies to stresses that recovery from COVID-19 provides strong immunity, which public health agencies denied, leading to vaccine mandates. He notes that, early in the pandemic, there was a consensus that masks were not particularly effective in controlling the spread of a highly infectious respiratory disease. However, this consensus changed overnight, and the government began promoting the use of cloth masks, which may have led to unnecessary deaths. Additionally, he criticizes U.S. school closures despite evidence that children do not drive COVID-19 spread and points out the importance of considering the risk-benefit balance when vaccinating children, supporting vaccines for older individuals while questioning their necessity for kids.

Dr. Jay Bhattacharya | CDC shifts on Covid vaccine "prevention recommendations" WATCH VIDEO

Politicization of Science: Dr. Bhattacharya states that the COVID-19 pandemic response became heavily politicized, explaining that political considerations, rather than pure science, influenced decisions. He points to cases where political leaders prioritized specific measures or public opinion over scientific evidence. This included lockdowns, mask mandates, and vaccine distribution. He highlights the role of high-profile figures, such as Dr. Anthony Fauci, in the politicization of science by equating their positions with scientific consensus.

Media Bias: Dr. Bhattacharya accuses the media of presenting a biased narrative during the pandemic, claiming that mainstream media outlets favored a particular perspective, often aligned with the government's stance. He reports that many journalists did not critically evaluate information provided by public health agencies; instead, they accepted official press releases without rigorous analysis. Dr. Bhattacharya suggests that the media portrayed dissenting voices, like his own, as "conspiracy theories" or marginalized them as "right-wing nut cases." He argues that this biased reporting prevented a balanced discussion of various scientific ideas related to the pandemic, which ultimately hindered the public's ability to make informed decisions.

Lack of Scientific Consensus: Dr. Bhattacharya suggests that there was a lack of scientific consensus on various pandemic-related issues. He mentions that the majority of scientists may have shared concerns but chose to remain silent due to fear or other reasons, which illustrates how the perception of unanimity was not accurate.

Influence of Public Health Agencies: He points out that public health agencies, like the CDC and NIH, play a significant role in shaping public health policies. Their statements often carry weight due to their perceived expertise and authority. However, he argues that these agencies, despite having limited scientific evidence, presented their recommendations as if they were firmly grounded in science.

Importance of Diverse Scientific Perspectives in Science Journalism: Dr. Bhattacharya stresses the importance of diverse scientific perspectives and the need for journalists to represent a range of views. He suggests that this can lead to more balanced and informed reporting. He advises journalists to engage in good-faith discussions with different scientists and present their ideas fairly to the public. Dr. Bhattacharya mentions that science journalists must rely on their experience to identify when to critically evaluate scientific claims. He argues that being an effective science journalist requires a deep understanding of how science operates and how to assess different viewpoints.

Betrayal of Public Trust: Dr. Bhattacharya points out that public health agencies need to be transparent and honest in their communication. When they present recommendations that lack substantial scientific backing, they risk betraying the trust of the public. He suggests that the public's trust in these agencies is eroded when they do not differentiate between solid scientific evidence and preliminary findings.

False Facts of COVID Hospitalizations, with Dr. Jay Bhattacharya WATCH VIDEO

Politicization of COVID-19 Response: Dr. Bhattacharya emphasizes that the pandemic response became politicized. Cases were used to stoke fear, but it's crucial to focus on hospitalizations and death rates to assess the severity of the pandemic. He highlights that the media and public health agencies have misled the public.

Hospitalization Overstatements: Dr. Bhattacharya mentions an audit that found COVID-19 was often cited on death certificates, even when other factors were more significant contributors to deaths. He points out that hospital financial incentives have led to potential overdiagnosis of COVID-19 patients, which inflated hospitalization numbers.

Incentives for Hospitalization: Hospitals received significant financial incentives for admitting COVID-19 patients. For instance, they received over $50,000 extra for each COVID-19 Medicare patient. This financial incentive may have contributed to the overdiagnosis of COVID-19 cases.

Misinterpreting Hospitalization Data: Dr. Bhattacharya cites studies indicating that nearly half of hospitalized COVID-19 patients may have had mild or asymptomatic cases. This includes both vaccinated and unvaccinated patients, implying that the severity of the disease might not be as dire as portrayed. Bhattacharya stresses that the media do not accurately interpret hospitalization data, and hospital systems should be considered as a whole. Even when some hospitals are stressed, the entire healthcare system might not be overwhelmed.

James Lyons-Weiler, Ph.D.

Website
Wikipedia

- Dr. Lyons-Weiler earned his Bachelor of Science in Biology from Indiana University of Pennsylvania.
- He received his Master's degree in zoology from the University of Connecticut.
- Dr. Lyons-Weiler obtained his Ph.D. in Ecology, Evolution, and Conservation Biology from the University of Nevada in Reno.
- He held various academic positions in the departments of Pathology, Imunology, Bioinformatics and Biomedical Sciences, at institutions such as the University of Pittsburgh, the University of Florida, and the University at Albany, State University of New York.
- Dr. Lyons-Weiler's research has primarily focused on genetics and genomics, applied to the understanding of disease etiology, evolution, and epidemiology.
- He has authored numerous peer-reviewed scientific papers, book chapters, and books. His publications have covered a wide range of topics, including cancer biology, autism, infectious diseases, and evolutionary genetics.
- Dr. Lyons-Weiler has developed and applied various statistical and computational methods in his research, with a focus on analyzing large-scale genomic data to extract meaningful biological insights.
- He has been an advocate for the transparency and integrity of scientific research.

Dr. James Lyons-Weiler's Coronavirus Research

WATCH VIDEO

Politicization of Health: Dr. Lyons-Weiler criticizes the politicization of public health, particularly the response to the COVID-19 pandemic. He accuses public officials of making decisions based on politics rather than scientific evidence and data.

Safety Concerns with Coronavirus Vaccines: Dr. Lyons-Weiler raises concerns about the safety of coronavirus vaccines, citing historical issues with coronavirus vaccine development. He mentiones the concept of "disease enhancement due to pathogenic priming," where vaccinated animals experience more severe diseases upon exposure to the wild-type virus.

Unsafe Epitopes in SARS-CoV-2: He notes that his peer-reviewed research identified unsafe epitopes (parts of proteins that can trigger immune reactions) in most of the proteins of the SARS-CoV-2 virus. He expresses concern about the potential for autoimmune responses caused by these unsafe epitopes.

Lack of Animal Trials: He criticizes the FDA for allowing vaccine manufacturers to skip animal trials for coronavirus vaccines, arguing that this decision was risky and does not adequately assess vaccine safety.

Serious Adverse Events: Dr. Lyons-Weiler mentioned that 21% of participants in the Moderna vaccine trial experienced serious adverse events. He called for transparency in vaccine trials and the reporting of such data.

Treatment vs. Vaccination: He highlighted the effectiveness of treatments for COVID-19, such as corticosteroids and antivirals. He criticized the focus on vaccines without adequate consideration of other treatment options.

Vaccine Mandates & Prior Immunity: Dr. Lyons-Weiler argued that mandating coronavirus vaccines would be disproportionate given the lower mortality rate in younger populations. He stressed the importance of not discounting prior immunity to coronaviruses, whether from exposure to similar viruses or from previous infections.

PCR Testing: Dr. Lyons-Weiler expressed concern about PCR testing, citing studies that showed false positives and negatives. He criticized the overreliance on testing and contact tracing, which he believed led to unnecessary economic disruptions.

Use of Cleaning Compounds: He mentioned concerns about the use of certain cleaning compounds in schools and the potential harm they could cause to students' reproductive systems and health.

National Vaccine Injury Compensation Program: Dr. Lyons-Weiler criticized the National Vaccine Injury Compensation Program, alleging corruption and conflicts of interest within the system.

Dr. Lyons-Weiler Lipid - Nanoparticles in COVID Vaccines and Your Health

WATCH VIDEO

Liquid Nanoparticles and Inflammation: Dr. Lyons-Weiler discusses a study that explored the effects of liquid nanoparticles in vaccines. These particles can create inflammation and inhibit the immune response, which raises concerns about the long-term impact on health. This is particularly relevant in the context of booster shots and repeated vaccinations.

Rushed Vaccine Development: He points out that, due to the rush to market and the Operation Warp Speed initiative, some COVID-19 vaccines have not undergone sufficient safety studies. The condensed timeline didn't allow for comprehensive vaccine safety research.

Immune Reactions: Dr. Lyons-Weiler explained that injecting foreign substances into the body can trigger immune reactions, which is not surprising. However, the extent to which these reactions affect the immune system is a key concern, especially in the context of influenza virus reactions in a mouse study.

Heterologous Immunity: He discusses the concept of heterologous immunity, where the immune response triggered by the liquid nanoparticles can affect the response to unrelated infections, and this was observed in male mice even in their offspring.

Pathogenic Priming: The concept of pathogenic priming was brought up, where exposure to certain vaccines might prime the immune system for a more severe reaction to subsequent infections. Dr. Lyons-Weiler discussed his own study on this topic, published in 2020.

Standing Up to Misinformation: He highlights the importance of standing up to misinformation and manipulative tactics used to spread false information, and the need for individuals to take a stand and educate themselves.

Dr. James Lyons-Weiler, Dr. Jessica Rose - Vaccine Choice Canada

WATCH VIDEO

Vaccine Adverse Event Reporting System (VAERS) Data: Dr. Jessica Rose discusses the key findings from her analysis of VAERS data, and highlights a notable surge in adverse event reports for COVID-19 vaccines over the past decade, with a significant increase in reported deaths compared to other vaccines over the past ten years. The discussion emphasizes the scale and seriousness of the adverse events, especially the number of reported deaths.

Professional Response to the Data: The discussion explores why medical professionals may not be more aware of concerning VAERS data. Dr. Lyons-Weiler suggests that many healthcare professionals rely on a culture of official guidance which, along with financial incentives tied to COVID-19 treatments, can deter them from seeking alternative perspectives or being informed about adverse events.

Misinformation and Censorship: Participants address the handling of vaccine risk information, including denial and confusion tactics, and explain how authoritative bodies aim to suppress dissent in order to uphold a positive public perception of vaccinations, which hinders open and honest discussions about potential adverse events.

Data Transparency and Safety Monitoring: Dr. Lyons-Weiler stresses continuous data transparency and robust safety monitoring. He criticizes health authorities like the FDA and CDC for inadequately fulfilling their regulatory roles, especially in monitoring safety data. He also questions the ongoing emergency use authorization, considering the pandemic's no longer an emergency.

Adverse Event Reporting: Dr. Lyons-Weiler mentions numerous adverse event reports in systems like VAERS and the Yellow Card system, including deaths, neurological problems, cardiovascular issues, and birth defects. He points out that these reports should be openly and regularly shared with the public, but this hasn't been happening adequately.

Pathogenic Priming and Antibody-Dependent Enhancement: Dr. Lyons-Weiler discusses pathogenic priming, referencing studies linking antibodies to placenta proteins and miscarriages due to the spike protein's similarity. He raises concerns about long-term effects on fertility and autoimmune responses, and also notes that pathogenic priming and antibody-dependent enhancement were known before COVID-19 vaccine rollout, citing examples with other viruses like SARS and MERS where vaccinated animals suffered more severe disease.

Real-Time Reporting System: Dr. Jessica discusses creating a real-time adverse event reporting system, akin to COVID-19 tracking, for transparently monitoring vaccine adverse events.

Masanori Fukushima, Ph.D.

Website
OMICS Online

- M.D. from Nagoya University's Faculty of Medicine in 1973.
- Ph.D. from Kyoto University's Faculty of Medicine in 1979.
- Professor Emeritus at Kyoto University.
- Director and Chairman of Translational Research Informatics Center (TRI) at Foundation for Biomedical Research and Innovation at Kobe (FBRI).
- Previously served as Deputy Director of Internal Medicine at Aichi Cancer Center, Professor of Pharmacoepidemiology at Kyoto University, and Director of Outpatient Oncology Unit at Kyoto University Hospital.
- Over 25 years of experience in standard cancer treatment and reforming Japan's medical care system.
- Actively involved in building the clinical trial infrastructure, with a focus on translational research.
- Advocates for the use of CDISC Standards in academic research for comprehensive, harmonized data standardization.
- Supervises national translational research promotion programs conducted by the government of Japan.

Dr. Masanori Fukushima: Vaccine Damage Is Now A Global Problem, Billions Of Lives Are At Risk

WATCH VIDEO

Dr. Fukushima highlights concerns about vaccines, criticizing their conception and administration processes. He questions the lack of academic rigor in their development and raises alarm about potential adverse effects, especially regarding widespread fatalities and health issues post-vaccination. Fukushima emphasizes the need for transparent reporting and accountability in addressing vaccine-induced complications, challenging the suppression of natural immunity and disputing government data on vaccine effectiveness and breakthrough infections.

Misconceptions Surrounding Vaccines: Dr. Fukushima criticizes the initial misconceptions about vaccines, emphasizing the importance of translating guidelines correctly. He highlights the effectiveness of steroids and how promptly implementing their use, despite initial skepticism, notably decreased mortality rates.

Lack of Academic Rigor in Vaccine Development: He critiques the lack of academic rigor in the development of vaccines and condemns those responsible without robust scientific procedures. Dr. Fukushima questions the global concerns regarding vaccine-related adverse effects.

Adverse Effects and Global Impact: The discussion centers on recent papers stating potential adverse effects post-vaccination and their global implications. He raises concerns about millions of lives potentially being endangered due to the vaccination's adverse reactions and challenges public health authorities to provide evidence contradicting issues raised in academic discussions.

Cardiovascular and Health-Related Impacts: Dr. Fukushima highlights adverse health effects post-vaccination, particularly focusing on cardiac and circulatory issues, suggesting a link between post-vaccine health concerns and increased fatalities.

Ignoring Scientific Evidence and Consequences: He chastises the disregard for scientific and medical insights in favor of imposing vaccination, emphasizing the dire consequences of ignoring established scientific and medical practices. He stresses the importance of eliminating misinformation and misleading practices in the healthcare system.

Impacts on Immune System and Breakthrough Infections: Dr. Fukushima expresses concerns about vaccine-induced alterations in the immune system, especially relating to the reduced effectiveness of natural immunity. He emphasizes the prevalence of breakthrough infections among vaccinated individuals, contrasting with official claims.

Accountability and Public Awareness: He urges transparency and accountability in vaccine-related discussions, advocating for public disclosure of vaccine-related data and urging lawmakers and public figures who advocate vaccination to disclose their vaccination status.

Dr. Fukushima's presentation encompassed concerns about vaccine-related misconceptions, academic integrity, adverse effects, immune system impacts, and the importance of transparent discussions and accountability in public health.

Dr. Masanori Fukushima and Dr. Reiner Fuellmich discuss mass vaccination campaigns WATCH VIDEO

Dr. Fukushima and Dr. Fuellmich delve into critical issues surrounding COVID-19 vaccinations and drug safety.

Past Drug Tragedies and Regulatory Reforms: The discussion revolved around past drug tragedies, notably the thalidomide disaster. Fukushima highlighted Japan's response to the thalidomide tragedy, leading to the enforcement of regulations such as Good Clinical Practice (GCP), informed consent, and international harmonization standards. These reforms were responses to catastrophic incidents caused by drugs like thalidomide, AIDS contamination, and others that shaped drug regulation in Japan.

COVID-19 Vaccination Campaign and Safety Concerns: Professor Fukushima expressed skepticism about mRNA vaccines, citing the modified nature of messenger RNA and potential dangers from non-biological manipulations. The focus shifted to concerns about adverse reactions and deaths post-vaccination in Japan. He discussed the official reporting system for adverse events, highlighting the government's initial reluctance to recognize the reported deaths and adverse reactions post-vaccination. Fukushima underscored the importance of investigating these incidents and the slow yet emerging response from the Ministry of Health and Welfare.

Vaccine-Related Deaths and Data Accuracy: The conversation questions the accuracy of government data on vaccine-related deaths, suspecting an underestimation of actual numbers. It highlights bureaucratic hurdles and insufficient information contributing to this disparity, impacting the disclosure of deaths and injuries. Causality assessment challenges and concerns about withheld mortality data suggest a possible mismatch between vaccine effectiveness and officially reported figures.

Nature of mRNA Vaccines: The conversation explores the nature of mRNA vaccines, focusing on their categorization as gene therapy and the widespread misunderstanding of this categorization. The speaker explains the mechanism of mRNA vaccines and the potential risks associated with lipid nanoparticles used in these vaccines, highlighting their ability to reach various body tissues, including the brain. The potential impact on cellular function, inflammatory responses, and autoimmune conditions due to the spread of nanoparticles is discussed. The conversation emphasizes the need for thorough investigations into post-vaccination syndromes and the concerns related to genetic products used in the injections.

Government Disregard for Autopsy Findings on Post-Vaccination Deaths: The conversation emphasizes the significance of autopsies in comprehending adverse events post-vaccination, citing cases of myocardial rhabdomyolysis leading to sudden deaths. It underscores the necessity of altering current medical practices for better post-vaccination health monitoring. Specifically, a case is highlighted where a healthy individual died due to myocardial rhabdomyolysis after the second vaccine dose, emphasizing the importance of autopsies and thorough health observation after vaccination. Additionally, the discussion condemns the government's dismissal of autopsy reports related to post-vaccination deaths, indicating a lack of acknowledgment or assessment by authorities. This situation prompts the need for legal action, showcasing Professor Fukushima's uncommon resistance against the government's neglect, contrary to Japan's typical compliance with authority.

Long-Term Effects of Vaccination: Concerns are expressed about the potential long-term effects of COVID-19 vaccinations. Notably, an increase in excess mortality rates following vaccination is observed, raising alarms about potential adverse impacts. There's a call for comprehensive analysis and understanding of these mortality patterns, particularly to ascertain if the excess mortality is directly linked to vaccination. Mathematical interpretations presented by Professor Nakamura at Tokyo University of Science are considered crucial in understanding these patterns.

Post-Vaccination Syndrome and Diagnosis Criteria: The conversation emphasizes the urgency of establishing diagnostic criteria for post-vaccination syndrome. This includes the need for clear-cut laboratory testing methods to detect changes at the cellular and molecular levels, especially regarding the spike protein in tissues or blood. The establishment of categories for different types of post-vaccination patients, based on their health status before and after vaccination, is also emphasized.

Immune System Impact and Disease Explosion: There's agreement regarding the destructive impact of mRNA vaccines on the immune system, leading to a loss of its protective function. The consequence seems to be a surge in diseases that were previously held in check, which explode in severity following vaccination. Discussions point to a paper by Stephanie Seneff and Mark Rux that highlights this phenomenon, indicating the need for doctors to base patient care on this research.

Arne Burkhardt, Ph.D. Privatdozent

Website
Wikipedia

- Dr. Burkhardt obtained his Doctor of Medicine degree from the University of Munich in 1971.
- Certified in medicine from the University of Kiel, Germany, and as a pathologist from the University of Hamburg.
- Became a Privatdozent (post-Ph.D. degree in Germany) at the University of Hamburg in 1979 and later a Professor at the University of Bern, Switzerland, in 1988.
- Held various positions in pathology throughout his career, serving as a scientific assistant at the University of Heidelberg and University of Hamburg, a senior pathologist at the University of Bern, and eventually heading the department of pathology at Lehrkrankenhaus University Tübingen, Reutlingen, Germany, since 1991.
- Dr. Burkhardt focused his research on various aspects of pathology, particularly on oral cancers, laryngeal tumors, and tissue markers for potentially malignant lesions.
- Authored and contributed to several books and scientific articles focusing on pathology, oral cancers, laryngeal tumors, and related subjects.
- Member of the International Association of Oral Pathologists, and served as a councilor from 1992 to 1996.

Pathologist Dr. Arne Burkhardt, EU Parliament 2023: How COVID Vaccines Kill You, Immune Self-Attack

WATCH VIDEO

Dr. Burkhardt addresses concerns over vaccination-related deaths and conducts a review of autopsies and biopsies to reevaluate these cases. They focus on uncovering new disease entities caused by a toxin produced internally after vaccination. Autopsy findings show that vaccination has a significant impact on the death process in 77% of cases, contrary to earlier reports attributing deaths to natural causes without proper examination. The presentation also discusses Sudden Adult Death Syndrome (SADS) and the impact of the vaccine on various organs and tissues, particularly endothelial tissues. The presence of spike proteins in multiple organs, especially vessels, leads to irreversible damage, physical weakness, neurological failures, premature aging, and potential psychological impacts. Dr. Burkhardt expresses concern about long-term consequences, such as higher blood pressure and premature aging due to the loss of elastic fibers in arterial vessels. They emphasize the need for public awareness regarding these findings and their implications for long-term health.

Histopathological reevaluation of serious adverse events and deaths following COVID-19 vaccination | Pandemic Strategies: Lessons and Strategies conference in Stockholm Sweden (January 2023)

WATCH VIDEO

Dr. Arne Burkhardt's presentation explored post-vaccination autopsy findings, analyzing 51 deceased individuals and four living cases. Initially prompted by concerns from relatives regarding deaths occurring after vaccination, Burkhardt's team embarked on an extensive scientific examination.

The research uncovered compelling connections between vaccination and approximately 80% of the deaths studied. They identified profound changes within tissues, especially in larger vessels where endothelial cell damage was prevalent. The endothelial damage manifested as vacuolar changes and a notable presence of spike protein, particularly in the endothelium of various organs.

Cholesterol crystals resembling foreign bodies and amyloid deposits were observed in vessel walls, notably affecting tissues in the spleen, brain, and heart. Burkhardt's team also noted specific organ lesions, such as myocarditis, lung alveolitis, lymphocytic nodules, and skin vasculitis, each showing the presence of the spike protein.

An alarming finding emerged in relation to the spike protein's presence in the testes, suggesting potential impacts on reproductive tissues and fertility. Furthermore, there were indications of vascular issues and blood clot formations, causing significant health concerns.

Burkhardt concluded his presentation with a pressing call to halt vaccination, citing the gravity of the autopsy findings and the urgency to reconsider the continuation of vaccination campaigns.

Pathology of vaccine deaths and vaccine injuries | Pathology Conference

WATCH VIDEO

Dr. Arne Burkhardt's presentation is a comprehensive analysis that delves into the intricate aspects of COVID-19 post-vaccination deaths, associated tissue damage, vaccine compositions, injection techniques, diagnostic practices, and future implications. His meticulous investigation unveils multifaceted concerns and crucial observations, encompassing various aspects of vaccination effects on the human body.

Background and Methodology: Dr. Burkhardt, a pathologist with 40 years of experience, initially expected to offer reassurance to families regarding post-vaccination deaths. However, upon examining cases, unexpected findings emerged, leading to an extensive investigation involving an international team of pathologists, biologists, and physicists.

The study involved collaboration among ten pathologists, coroners, biologists, and physicists. It encompassed 25 deaths, samples from living patients, postmortems, and evaluations spanning routine histology to special methods. Most deaths occurred at home within a span of seven days to six months post-vaccination.

Vascular Lesions: One significant finding involves vascular lesions: small vessel issues, thrombocyte aggregates, microthromboses, obliterations, texture disruptions, dissections, perforations, and thromboses without arteriosclerosis. These abnormalities occurred in major and minor vessels, particularly evident in the aorta. Images revealed detached spindle cells, lymphocyte infiltrates, and disruptions in vessel structure and layers, indicating alterations not attributable to post-mortem degradation.

Spike Protein Presence: The team attempted to prove the presence of spike proteins within tissues using immunohistological methods. Positive reactions were observed in damaged vessels, particularly in capillaries, arterioles, and the aorta, indicating a correlation between the lesions and the spike protein from vaccination.

Other Organ Findings: Apart from vascular issues, alterations were observed in lymphatic organs such as the spleen and lymph nodes. These included arteriolysis, intravasal and extravasal objects, and specific spike protein expressions in the spleen.

The study also highlighted myocarditis, alveolitis, lymphocytosis, and peculiar observations in the heart muscle, where mast cells with degranulation and active substances like histamines were found.

Brain and Nervous System, and Necrotizing Encephalitis: Intracerebral findings included transfection-associated encephalitis, lymphocyte infiltration in blood vessels, dura mater, and partial hypophysis necrosis. Dr. Burkhardt highlighted a case in which post-mortem examination revealed necrotizing encephalitis, vasculitis of aorta and coronary artery, along with a mild lymphocytic encephalitis. The crucial finding was the presence of spike protein in the brain cells, suggesting the vaccine's impact on the blood-brain barrier.

Tissue Reactions and Unidentified Structures: Examining biopsies and resections, they observed the presence of spike protein in periappendix tissues, indicating reactions in various tissues beyond the brain. Additionally, they identified unidentified structures in muscle, fatty tissues, and spleen vessels that lacked nuclei and appeared foreign, suggesting an unexpected tissue modification post-vaccination.

Foreign Substances in Vaccines: Dr. Burkhardt discussed the presence of foreign substances in vaccine materials. Through scanning electron microscopy, he highlighted metallic objects, glass-like particles, and carbon and oxygen compounds in certain vaccines (BioNTech and Moderna). However, he indicated that these findings were not confirmed or verified yet.

Vascular Injection and Embolic Consequences: There were concerns raised about the size of vaccination sites, with evidence suggesting that the needle could easily enter blood vessels without proper aspiration. This led to speculations about potential embolic consequences and a delay in acknowledging and implementing safer practices by health authorities.

Production of Spike Proteins: The presentation challenged the understanding of where spike proteins are produced post-vaccination. Dr. Burkhardt showed that besides muscle cells, numerous other body cells produced spike proteins, raising questions about the scope of their production and their impact on different organs or tissues.

Doctor-Patient Interactions and Outcomes: Dr. Burkhardt mentioned three phases of interactions post-vaccination: families of the deceased questioning causes; victims experiencing health issues dismissed as unrelated to vaccination; and medical practitioners avoiding discussions about vaccine-related concerns, even after experiencing adverse outcomes.

Surveillance Studies

Surveillance studies encompass systematic and ongoing collection, analysis, interpretation, and dissemination of health-related data. In the context of vaccination campaigns during a pandemic, these studies play a pivotal role in monitoring the real-time effects on public health. They scrutinize not only the immediate consequences but also track long-term trends and potential ramifications, allowing for a comprehensive assessment of the vaccine's impact beyond clinical trials.

In this chapter, a comprehensive exploration unveils a divergent perspective on the impact of COVID-19 vaccination campaigns on public health. Contrary to the prevailing narrative, this section offers a compilation of meticulous surveillance studies that stand in contradiction to the established discourse. They investigate various facets, from vaccine-associated mortalities in different regions of the world to analyses of mortality rates post-vaccination rollout.

Each study raises poignant questions about the safety profiles and actual impacts of COVID-19 vaccines, encompassing a breadth of investigations that challenge the conventional understanding of the safety and efficacy of the novel technologies. In a significant divergence from the mainstream narrative, which touts the safety and necessity of COVID-19 vaccinations, these surveillance studies present substantial evidence that urges a reassessment of the assumptions surrounding these vaccinations, and serve as poignant reminders of the importance of critical inquiry and robust analysis in shaping public health policies and decisions.

FORENSIC ANALYSIS OF THE 38 SUBJECT DEATHS IN THE 6-MONTH INTERIM REPORT OF THE PFIZER/BIONTECH BNT162B2 MRNA VACCINE CLINICAL TRIAL

SOURCE: https://ijvtpr.com/index.php/IJVTPR/article/view/86/224

Key Points

- The analysis of the Pfizer/BioNTech BNT162b2 mRNA vaccine trial (C4591001) found no significant difference in the number of deaths between the vaccinated and placebo arms for the first 20 weeks of the trial. However, after week 20, deaths in the vaccinated continued, while deaths in the placebo slowed and plateaued.
- There was evidence of a 3.7-fold increase in deaths due to cardiac events in the BNT162b2 vaccinated individuals compared to those who received the placebo, and discrepancies were found in the reporting of subject deaths compared to the data reported by Pfizer/BioNTech.
- The study raised concerns about the accuracy and transparency of the reported findings, questioned the adequacy of the 20-week duration of the clinical trial, and pointed out flaws in the clinical trial oversight and reporting processes that may have prevented a comprehensive evaluation of the vaccine's safety and efficacy.

Analysis of Trial Data: The research paper conducted a forensic analysis of the original data from the Pfizer/BioNTech BNT162b2 mRNA vaccine clinical trial (C4591001). The study focused on the 38 trial subjects who died between July 27, 2020, and March 13, 2021, as part of the trial. The trial involved 44,060 subjects who were equally distributed into two groups and received either the BNT162b2 mRNA vaccine or a placebo. Surprisingly, the analysis found no significant difference in the number of deaths between the vaccinated and placebo arms for the first 20 weeks of the trial.

After week 20, when the placebo subjects were unblinded and given the option to receive the BNT162b2 vaccine, deaths among those sticking with the placebo slowed and eventually plateaued. In contrast, deaths in the BNT162b2 vaccinated subjects continued at the same rate. The analysis revealed inconsistencies between the subject data listed in the 6-Month Interim Report and in publications authored by Pfizer/BioNTech trial site administrators.

Increase in Deaths from Cardiac Events: The study found evidence of an over 3.7-fold increase in the number of deaths due to cardiac events in the BNT162b2 vaccinated individuals compared to those who received only the placebo. The delayed reporting of subject deaths into the Case Report Form obscured the cardiac adverse event signal and allowed the Pfizer/BioNTech Emergency Use Authorization to proceed unchallenged.

Discrepancies in Reporting: The summary also highlighted discrepancies in reports on subject deaths, particularly in comparison to data reported by Pfizer/BioNTech, Polack et al. (2020), and Thomas et al. (2021). The discrepancies found in the data presented to the FDA during the EUA application and the lack of update on the results during the December 10, 2020 presentation are of concern.

Concerns About Accuracy and Transparency: The report in question examines the Pfizer/BioNTech BNT162b2 vaccine clinical trial data and raises concerns about the accuracy and transparency of the reported findings. The study focuses on discrepancies related to the reporting and recording of deaths, specifically highlighting a 2-fold increase in deaths due to cardiac events in subjects who received the BNT162b2 vaccine compared to the placebo group. The analysis indicates that Pfizer/BioNTech knew of 10 more subjects who died between November 14 and December 10, 2020, but did not disclose this information in a timely manner. The paper also questions the decision to halt the placebo-controlled portion of the trial and raises concerns about the lack of transparency and the reporting errors in the trial reports.

Long-term Safety Evaluation: Furthermore, the study questions the adequacy of the 20-week duration of the clinical trial to fully evaluate the safety of the mRNA-LNP vaccine. It emphasizes the need for longer-term safety evaluations and highlights the potential risks associated with the use of the Spike protein as the encoded antigen in the vaccine. The article also points out flaws in the clinical trial oversight and reporting processes, suggesting that these factors may have prevented a comprehensive and accurate evaluation of the vaccine's safety and efficacy.

COVID-19 VACCINE-ASSOCIATED MORTALITY IN THE SOUTHERN HEMISPHERE

SOURCE: https://correlation-canada.org/wp-content/uploads/2023/09/2023-09-17-Correlation-Covid-vaccine-mortality-Southern-Hemisphere-cor.pdf

Key Points

- The research paper finds no positive impact of COVID-19 vaccines on all-cause mortality (ACM) in 17 equatorial and Southern-Hemisphere countries, with peaks observed after vaccine deployment.
- This study establishes vaccine-dose fatality rate (vDFR) and its age-related exponential relationship, indicating a globally significant vaccine-induced mortality larger than reported, urging caution in prioritizing elderly residents for COVID-19 vaccination.
- The paper includes in-depth data analysis and methods supporting the link between vaccine rollouts and mortality peaks, concluding a strong causal association between COVID-19 vaccine administration and excess ACM. Calls for urgent review of public health policies and valid risk-benefit analyses.

Findings

The research paper explores the link between the introduction of COVID-19 vaccines and peaks in all-cause mortality (ACM) in 17 equatorial and Southern Hemisphere countries. Contrary to expectations, the study reveals no positive impact of COVID-19 vaccines on ACM. Instead, it identifies elevated ACM levels during the summer of 2022 in these regions, coinciding with the widespread rollout of COVID-19 vaccine booster doses. The research establishes the vaccine-dose fatality rate (vDFR) and its exponential correlation with age. The findings imply a globally widespread and more significant vaccine-induced mortality than reported, emphasizing the necessity for additional analyses before prioritizing COVID-19 vaccination for elderly residents. The paper includes in-depth data analysis and methodologies supporting the association between vaccine deployment and mortality peaks.

Detailed Analysis: The research paper investigates the association between rapid COVID-19 vaccine dose rollouts and all-cause mortality (ACM) peaks. It utilizes ACM data to detect events causing death and to determine the vaccine-dose fatality rate (vDFR) and its age relationship. The paper discusses specific examples, such as the ACM peak in Australia and similar phenomena in other Southern Hemisphere and equatorial countries. The study presents detailed data from 17 equatorial and Southern Hemisphere countries, encompassing about 9.10% of the global population and approximately 10.3% of global COVID-19 vaccine injections, indicating an excess all-cause mortality (ACM) in all 17 countries. It concludes that there is a strong evidence for a causal association between COVID-19 vaccine administration and excess ACM. Further, the paper discusses the implications of these findings on the public health policy of prioritizing elderly individuals for COVID-19 vaccination. The study reveals an unprecedented magnitude of fatality from COVID-19 vaccine injections, highlighting the need for urgent review of current public health policies and valid risk-benefit analyses.

Comprehensive Examination: The research paper explores the association between rapid COVID-19 vaccine dose rollouts and all-cause mortality (ACM) peaks. It investigates the use of ACM data for detecting and characterizing events resulting in death and determines the vaccine-dose fatality rate (vDFR) and its relationship with age. The study examines specific examples such as the ACM peak in Australia and the observation of similar phenomena in other Southern Hemisphere and equatorial countries. The paper provides a comprehensive analysis of excess mortality and its relationship with the COVID-19 pandemic and vaccination efforts.

Methodology and Data Sources: The research paper investigates the association between rapid COVID-19 vaccine dose rollouts and all-cause mortality (ACM) peaks. It focuses on the use of ACM data for detecting and characterizing events causing death, determination of the vaccine-dose fatality rate (vDFR), and its relationship with age. Specific examples, such as the ACM peak in Australia, and similar phenomena in other Southern Hemisphere and equatorial countries, are highlighted. The paper also details the sources and types of data used, including vaccine administration and ACM, and the parameters used in applying the trend-line method to the data. Additionally, the paper discusses the correlation between COVID-19 vaccine-associated mortality and vaccination periods.

WESTERN AUSTRALIAN VACCINE SAFETY SURVEILLANCE – ANNUAL REPORT 2021

SOURCE: https://www.health.wa.gov.au/~/media/Corp/Documents/Health-for/Immunisation/Western-Australia-Vaccine-Safety-Surveillance-Annual-Report-2021.pdf

Key Points:

- The year 2021 saw a significant increase in vaccine doses administered in Western Australia, especially due to the COVID-19 vaccination program, resulting in a substantial rise in Adverse Events Following Immunisation (AEFI) reports, totaling 10,726.
- The overall AEFI rate reported by the Therapeutic Goods Administration (TGA) was 264.1 per 100,000 doses, with variations by vaccine brand. Comparison with the Vaccine Adverse Event Reporting System (VAERS) in the USA showed higher AEFI rates in WA, possibly due to reporting system differences.
- The surveillance system actively monitored specific adverse events of special interest (AESI) related to COVID-19 vaccines, such as anaphylaxis, thrombosis with thrombocytopenia syndrome (TTS), immune thrombocytopenic purpura (ITP), Guillain-Barré syndrome (GBS), myocarditis, and pericarditis. These monitoring efforts contributed to shaping recommendations by TGA and ATAGI.

Background and Data Overview: The Western Australian Vaccine Safety Surveillance Report 2021 presents data on adverse events following immunization (AEFI) reported to the Western Australia Vaccine Safety Surveillance (WAVSS) system for vaccinations received in 2021. The report highlights the impact of the COVID-19 vaccination program on vaccine surveillance. In 2021, 5,756,723 vaccine doses were administered in WA, with 3,948,673 individual doses of COVID-19 vaccine recorded. The increase in vaccine administration resulted in a significant increase in reports of AEFI, with WAVSS receiving 10,726 individual AEFI reports in 2021, up from 270 in 2020.

Vaccine Administration Increase vs. AEFI Reports Surge: In 2021, WA experienced a substantial increase in vaccine doses administered, primarily driven by the COVID-19 vaccination program. The total doses administered were 5,756,723, compared to 2,071,167 in 2020. The surge in vaccine administration was accompanied by a significant rise in AEFI reports, reaching 10,726 in 2021, compared to 270 in 2020. COVID-19 vaccines contributed to 97% of these reports.

AEFI Rates by Brand and Age Group: The report details AEFI rates by brand (Vaxzevria, Comirnaty, Spikevax) and age group, revealing variations in rates among different demographic categories.

Specific AESI Monitoring: The report provides detailed insights into the monitoring of specific AESI, including anaphylaxis, TTS, ITP, GBS, myocarditis, and pericarditis, offering a comprehensive assessment of safety concerns.

Specialist Clinic Activity: The report sheds light on the activities of specialist vaccine safety clinics, including referrals, appointments, and the types of cases handled, both for adults and children.

Robust Surveillance System: The Western Australia Vaccine Safety Surveillance (WAVSS) system demonstrated its robustness in monitoring adverse events following immunization, with a particular focus on the substantial increase in AEFI reports in 2021. The collaboration between WAVSS, TGA, and other immunization programs proved effective in actively monitoring specific AESI related to COVID-19 vaccines, contributing to national decision-making.

System Enhancements: The report highlighted significant changes and enhancements to the surveillance system in 2021, including direct reporting to TGA, inclusion of SmartVax, increased clinic capacity, and the establishment of the Expert Clinical Review Group, ensuring an agile response to the evolving vaccination landscape. The surge in AEFI reports reflected heightened public engagement, providing an opportunity for rigorous investigation and influencing national recommendations.

COMPARISON OF EUROPEAN DEATHS

SOURCE: https://www.hartgroup.org/country-comparison-of-deaths/

Key Points

- The research paper compared vaccination rates and excess mortality in European countries, finding a strong correlation between higher vaccination rates and lower excess mortality from July to December 2021, but this reversed from April to August 2022, with higher vaccination rates being associated with higher excess deaths.
- Varied correlations in booster uptake and excess deaths were found, with a weaker correlation in Western European countries and a 37% predictability of excess deaths based on first booster doses in Eastern Europe. The study also emphasized the need for further research into the complexity of the relationship between vaccination rates and excess mortality.
- The report expresses concern over the reversal of lower deaths in highly vaccinated countries and criticizes the UKHSA's claims of over 50% efficacy against death, suggesting a divergence between their estimates and real-world evidence.

Synopsis

The research paper compared the correlation between vaccination rates and excess mortality in European countries. Data from the European Centre for Disease Prevention and Control's vaccination tracker and Eurostat's excess deaths statistics were utilized for the analysis. It investigates the connection between COVID-19 vaccination rates and excess mortality in European countries, examining data from the end of 2021 to recent months. It observes a significant correlation, initially showing that more heavily vaccinated countries had lower excess mortality during the Delta wave. However, this trend shifted in the months following, with more vaccinated countries experiencing higher excess mortality. The conclusion raises concerns about the reversal of lower deaths in highly vaccinated countries and questions the validity of UKHSA's efficacy claims, emphasizing a perceived disparity between their estimates and real-world evidence.

Analysis of July to December 2021: During this period, a strong correlation was observed whereby countries with higher vaccination rates experienced lower excess mortality, with 55% of the variation explained by vaccination rates. This suggested a potential benefit of higher vaccination coverage during the Delta wave.

Analysis of April to August 2022: However, contrary to the previous period, the analysis of excess deaths from April to August 2022 revealed an inverse correlation. More heavily vaccinated countries showed higher excess mortality, with 46% of the variation predicted by vaccination rates. Additionally, a similar correlation was found for the first booster doses, indicating higher excess deaths in populations with increased booster uptake.

Regional Variations - Eastern vs. Western Europe: To address potential confounding factors, the data was separated for Eastern and Western European countries. In July to December 2021, the benefit observed in Eastern Europe retained a correlation between higher vaccination rates and lower excess mortality, while Western Europe showed no impact on mortality above a certain vaccination level. However, two outliers, Romania and Bulgaria, raised questions about the reliability of the correlation in Eastern Europe. In the more recent period (from April to August 2022), a strong correlation was observed in Western Europe, with increased excess deaths associated with higher booster uptake. In Eastern Europe, 37% of the variation in excess deaths could be predicted from first booster doses, suggesting a more pronounced impact of boosters on mortality in this region.

Conclusion:
The article concludes with a concern about the reversal of lower deaths in highly vaccinated countries observed in July to December 2021. It references similar work by Igor Chudhov, showing a correlation between boosters and mortality. Criticism is directed at the UKHSA, questioning the validity of their claims of over 50% efficacy against death, highlighting the divergence between their estimates and real-world evidence.

PERSEUS REPORT ON MHRA'S REGULATION OF THE COVID-19 VACCINES

SOURCE: https://perseus.org.uk/wp-content/uploads/2023/04/Perseus_MHRA_Main-Report-1-1.pdf

Key Points

- The report highlights serious shortcomings in the Medicines and Healthcare products Regulatory Agency (MHRA)'s regulation of Covid-19 vaccines, with significant safety issues and failures in responsibilities, including the absence of safety requirements for manufacturers and approvals for younger age groups and children without long-term safety data.
- Safety concerns about Covid-19 vaccines, including mRNA and viral-vector DNA technologies, are raised due to reported adverse events such as blood clotting, heart inflammation, neurological conditions, immune downgrading, and menstrual disorders. The MHRA's response to complaints about promotional claims about vaccine safety and efficacy, as well as transparency and accountability, is also criticized.
- The article calls for urgent measures to address the MHRA's regulatory shortcomings, including a pause on the use of Covid-19 vaccines, a full independent inquiry into the agency's regulatory processes and performance, and the implementation of measures to protect the public from potential risks associated with medicines and vaccines.

Regulation of Covid-19 Vaccines: The report on MHRA's Regulation of Covid-19 vaccines highlights serious shortcomings in the regulatory system and significant safety issues regarding the vaccines. The Medicines and Healthcare products Regulatory Agency (MHRA) has been found to have failed in its responsibilities, including the absence of safety requirements for manufacturers and approvals for younger age groups and children without long-term safety data. The report indicates that the MHRA did not act promptly on evidence of adverse reactions and failed to address problems with manufacturing and quality control.

Safety Concerns about Covid-19 Vaccines: The Covid-19 vaccines, which are different from traditional vaccines, use mRNA and viral-vector DNA technologies, raising concerns about long-term safety. The risks and benefits of the vaccines have not been balanced adequately, and adverse events associated with the vaccines have been widely reported, including blood clotting, heart inflammation, neurological conditions, immune downgrading, and menstrual disorders. The report also highlights specific instances of vaccine-related adverse events, including myocarditis, neurological conditions, and menstrual disorders.

Recommendations for Action: Overall, the report identifies several shortcomings in the MHRA's regulatory processes and performance, raising grave concerns about its ability to fulfill its statutory duty to protect the public from harm. The report calls for a pause on the use of Covid-19 vaccines to allow for proper investigation and a full independent inquiry into the MHRA's regulatory processes and performance.

Analysis of the MHRA's Practices: The article presents a comprehensive analysis of the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK, focusing on its regulatory practices, safety monitoring, funding sources, and conflicts of interest. The authors raise concerns about the MHRA's safety culture, risk assessment processes, safety monitoring methods, and the lack of independent safety audits. They also highlight the agency's reliance on industry funding and the potential for conflicts of interest. The authors criticize the MHRA's definition of "acceptably safe" for medicines, which they argue is relative and lacks a clear threshold for action if safety risks emerge. The paper also questions the agency's monitoring of COVID-19 vaccine safety, including its reliance on statistical analysis of Yellow Card reports and concerns about data bias.

Lack of Independent Safety Audits: Furthermore, the article discusses the lack of independent safety audits of both products and internal safety management processes at the MHRA. It raises questions about the agency's vulnerability to errors and omissions, as well as its governance and accountability processes.

INCREASED EMERGENCY CARDIOVASCULAR EVENTS AMONG UNDER-40 POPULATION IN ISRAEL DURING VACCINE ROLLOUT AND THIRD COVID-19 WAVE

SOURCE: https://www.nature.com/articles/s41598-022-10928-z

Key Points

- The study examines the relationship between COVID-19 vaccination and cardiovascular adverse events, specifically cardiac arrest (CA) and acute coronary syndrome (ACS), in the 16–39-year-old population using data from Israel's National Emergency Medical Services (EMS) from 2019 to 2021.
- The study found a significant 25% increase in CA and ACS calls from January–May 2021 compared to 2019–2020, which was associated with the rates of 1st and 2nd vaccine doses administered to this age group. There's no statistically significant correlation between the increase in cardiac-related emergency calls and COVID-19 infection rates within this age group during the same time frame.
- The study emphasizes the importance of incorporating EMS and other health data into vaccine safety surveillance systems to promptly investigate potential underlying causes of increased EMS calls and to better understand the potential risks associated with vaccination. It raises concerns about vaccine-induced severe cardiovascular side-effects, stresses the need for thorough investigation into individual cases, and underscores the importance of prompt identification and management of COVID-19 vaccine side-effects and outcomes.

Overview

Main Arguments and Substantiations: Vaccine Rollout and Cardiac Emergencies: The report unequivocally identifies a noteworthy surge of 25% in both CA and ACS calls during January–May 2021, aligning precisely with the administration of 1st and 2nd COVID-19 vaccine doses among individuals aged 16–39. This stark increase in cardiac emergencies strongly correlates with the timing of vaccine doses, signaling a concerning association between vaccination and cardiovascular-related health issues.

Lack of Direct Correlation with COVID-19 Infections: Despite the surge in COVID-19 infections during certain periods, the study highlights a lack of statistically significant correlation between increased cardiac-related emergencies and COVID-19 infection rates among the same age group. This underscores that the upsurge in cardiac emergencies doesn't seem directly linked to the prevalence of COVID-19 infections within this demographic.

Concerns about Undetected Cardiovascular Side-effects: The findings serve as a red flag, raising serious concerns about potential undetected severe cardiovascular side-effects associated with COVID-19 vaccination, particularly regarding myocarditis. The study prompts a critical examination of unexpected cardiac events among young individuals post-vaccination, calling for comprehensive investigation and monitoring to understand and mitigate these alarming adverse events.

Comprehensive Context: This extensive analysis spans two and a half years, encompassing periods before, during, and after the COVID-19 pandemic and vaccination rollout. Leveraging Israel's EMS dataset, the study meticulously examines the incidence of cardiac emergencies alongside vaccination rates and COVID-19 infections. The robustness of the findings emerges from the direct correlation between the increase in cardiac emergencies and vaccine doses administered to the 16–39 age group, establishing a worrying trend that calls for urgent investigation and action.

Implications and Recommendations: The report underscores the critical need to incorporate EMS data into vaccine surveillance systems, highlighting its invaluable role in promptly identifying concerning public health trends. It urges immediate, thorough investigations into potential adverse cardiovascular effects post-vaccination among young adults. Furthermore, it emphasizes the importance of public awareness regarding symptoms associated with myocarditis and related conditions post-vaccination, especially among the younger demographic.

THE ROLLOUT OF COVID-19 BOOSTER VACCINES IS ASSOCIATED WITH RISING EXCESS MORTALITY IN NEW ZEALAND

SOURCE: https://repec.its.waikato.ac.nz/wai/econwp/2211.pdf

Key Points

- Concerns about the lack of safety data and doubts about the benefits of mass booster doses of COVID-19 vaccines over targeted approaches have raised worries about potential risk. The rollout of boosters lacked robust evidence, relying on observational studies with potential biases, raising doubts about their safety and efficacy.
- Evidence from a study in New Zealand using time-series analysis of aggregate data and instrumental variables suggests an association between the rollout of booster doses and rising excess mortality, with approximately 16 excess deaths per 100,000 booster doses and an estimated economic value of over $1.6 billion.
- The research emphasizes the need for stronger evidence to support the mass use of boosters, highlighting potential biases in observational studies and the challenges in evaluating the risk-benefit ratio of booster doses. It calls for more rigorous studies and safety measures to accurately assess the impact of booster doses on public health and vaccination efforts.

Overview

The paper highlights the concerns regarding the lack of safety data and doubts about the benefits of mass boosting over targeted approaches. It discusses the potential risks associated with unnecessary boosting and its impact on public confidence in vaccination efforts. Additionally, the study addresses the evidence of rising excess mortality in New Zealand linked to the booster rollout, using time-series analysis of aggregate data and instrumental variables.

The association between booster rollout and rising excess mortality in New Zealand is examined using aggregate weekly data on excess mortality. The study utilizes an instrumental variables strategy to interpret the impacts of the booster dose rollout, demonstrating 16 excess deaths per 100,000 booster doses. This amounts to over 400 excess deaths from New Zealand’s booster rollout to date, with an estimated economic value of over $1.6 billion. The rise in excess mortality is observed in all age groups except the youngest.

The research also addresses the concerns around the shift in the risk-benefit ratio, emphasizing the need for stronger evidence to underpin the mass use of boosters. There’s a concern about the erosion of evidence-based medicine, as booster rollout decisions seem to rely on weaker observational studies instead of robust, large-scale trials. It highlights the potential biases in observational studies and the challenges in evaluating the risk-benefit ratio of booster doses. The study suggests that the potential risks associated with booster rollout may have been underestimated, calling for the discontinuation of further booster vaccinations as a safety measure.

The evidence provided shows a temporal association between booster rollout and rising excess mortality in New Zealand, with time-series analysis demonstrating a notable increase in excess deaths associated with the booster rollout. It particularly emphasizes the significant rise in mortality rates among age groups eligible for boosters, suggesting a causal link between booster doses and increased deaths. Through statistical analyses and instrumental variables estimation, the report quantifies the impact, estimating approximately 16 excess deaths per 100,000 booster doses given, leading to over 400 excess deaths attributed to New Zealand's booster rollout. The study extrapolates the excess mortality estimate to other countries, suggesting potential implications on a global scale. The paper emphasizes the ethical and economic implications of the booster rollout, advocating for more rigorous studies and safety measures to accurately assess the risk-benefit ratio of booster doses.

In conclusion, the research paper presents compelling evidence on the association between the rollout of COVID-19 booster vaccines and rising excess mortality in New Zealand. The findings raise important concerns about the potential risks and lack of robust evidence supporting the mass use of boosters, with significant implications for public health and vaccination efforts.

AGE-STRATIFIED COVID-19 VACCINE-DOSE FATALITY RATE FOR ISRAEL AND AUSTRALIA

SOURCE: https://correlation-canada.org/wp-content/uploads/2023/02/2023-02-09-Correlation-Age-stratified-vaccine-dose-fatality-Israel-Australia.pdf

Key Points

- The study focused on quantifying the vaccine-dose fatality rate (vDFR) of COVID-19 vaccines, finding a vDFR of 1% in India and 0.05% in Australia, with an exponential increase in vDFR with age for older adults.
- The paper established a large vDFR in elderly people, reaching 0.6% for the 80+ years age group in Israel and 1% for the 85+ years age group in Australia, indicating a significant increase in vDFR with age.
- The study used national all-cause mortality and vaccine rollout data to calculate the age-stratified vDFR, finding a non-exponential constant vDFR for young adults (vDFR ≈ 0.005%) and highlighting the need to prioritize age-stratified risk of fatality from the injection.

Analysis of the study's approach to quantifying the vDFR:

- The study used epidemiological methods applied to all-cause mortality and vaccine rollout data to quantify the vDFR.
- The method for age-stratification relied on plotting the all-cause mortality by time for different age groups.
- The study meticulously calculated the vDFR, taking into account the vaccination period and the number of vaccine doses administered, and highlighted the importance of considering age-specific risks when prioritizing vaccination efforts.

Overview

The research paper aimed to quantify the vaccine-dose fatality rate (vDFR) of COVID-19 vaccines, particularly focusing on age-stratified vDFRs for Israel and Australia. The study found that the vDFR increases significantly with age, being exponential with a doubling time of approximately 5.2 ± 0.4 years for older adults. The vDFR was found to be exponentially smaller for young adults, at approximately 0.005%. The findings indicated a large vDFR in elderly people, reaching 0.6% for the 80+ years age group in Israel and 1% for the 85+ years age group in Australia. Detailed autopsy studies, adverse effect monitoring, and peer-reviewed publications supported the understanding that COVID-19 vaccines can cause death. The study used national all-cause mortality and vaccine rollout data to calculate the age-stratified vDFR and found a non-exponential constant vDFR for young adults.

The approach to quantifying the vDFR involved using epidemiological methods applied to all-cause mortality and vaccine rollout data, and the method for age-stratification relied on plotting the all-cause mortality by time for different age groups. The study methodically calculated the vDFR, taking into account the vaccination period and the number of vaccine doses administered. The implications of the findings highlighted the need to prioritize age-stratified risk of fatality from the injection, as the study suggested that the public health notion of prioritizing elderly people for vaccination without sufficient evaluation of age-stratified risk was reckless.

In conclusion, the study provided empirical evidence of age-stratified vDFRs for COVID-19 vaccines in Israel and Australia, indicating a significant increase in vDFR with age and underscoring the importance of considering age-specific risks when prioritizing vaccination efforts. The study's approach to quantifying vDFR involved meticulous analysis of national all-cause mortality and vaccine rollout data, presenting robust evidence of the association between COVID-19 vaccine administration and an increase in mortality, particularly among elderly individuals.

PROBABLE CAUSAL ASSOCIATION BETWEEN AUSTRALIA'S NEW REGIME OF HIGH ALL-CAUSE MORTALITY AND ITS COVID-19 VACCINE ROLLOUT

SOURCE: https://correlation-canada.org/wp-content/uploads/2022/12/2022-12-20-Correlation-Australia-excess-mortality-vaccine-rollout.pdf

Key Points

- Following the COVID-19 vaccination rollout in Australia, there was a significant increase in all-cause mortality, estimated to be 31±1 thousand deaths, more than twice the deaths registered as COVID-19-related, and this increase was also observed following the rollout of booster doses.
- The paper provides thirteen numbered arguments supporting the conclusion that the excess mortality in Australia is causally associated with the COVID-19 vaccine, and it estimates the vaccine injection fatality ratio (vIFR) to be approximately 0.05%.
- The report dismisses the possibility of the mortality peak being caused by a heatwave and emphasizes the need for further investigation and consideration of the implications for public health and vaccine safety.

Research Findings

The research paper discusses the all-cause mortality patterns in Australia in relation to the COVID-19 vaccine rollout. The study reveals a significant increase in all-cause mortality in mid-April 2021, synchronous with the vaccine rollout aimed at high-risk residents. The excess mortality during the vaccination period (mid-April 2021 through August 2022) amounted to 31,000 deaths, more than twice the total number of deaths registered as being from or with COVID-19. This excess mortality was associated with the COVID-19 vaccine, and the corresponding vaccine injection fatality ratio (vIFR) was estimated to be approximately 0.05%.

The paper presents detailed data from Australia, including all-cause mortality by week, integrated mortality over time periods, and vaccine dose delivery. It also discusses the synchronicity between the step-wise increase in mortality and the vaccine rollout across all states in Australia, as well as a prominent peak in mortality in mid-January to mid-February 2022, synchronous with the booster rollout. The study provides illustrative figures and data analysis to support its findings.

Moreover, the paper compares the vIFR values from Australia to those from the USA and India, highlighting the different impacts of the vaccine rollout in various regions. The authors also address the question of whether the mid-January to mid-February 2022 mortality peak could be due to a heatwave and provide evidence to support the conclusion that it was not caused by a climatic heatwave.

Based on their analysis, the authors conclude that the excess mortality in Australia is causally associated with the COVID-19 vaccine rollout. They present thirteen numbered arguments to support their conclusion, highlighting the temporal association between the increase in mortality and the vaccine rollout, along with the impact on frail and vulnerable populations. The paper also cites other studies and presents historical and climatic data to strengthen its claims.

Summary and Implications

In summary, the paper provides a comprehensive analysis of all-cause mortality in Australia in relation to the COVID-19 vaccine rollout, using data, figures, and detailed reasoning to support the conclusion that the excess mortality is likely associated with the vaccine. The authors assert the need for further investigation and emphasize the importance of considering the impact of the vaccine rollout on vulnerable populations.

Research Papers

This chapter offers a compilation of meticulous investigations sourced from reputable scientific repositories like NCBI, Science Direct, Science.org, The Lancet, BJM, Pubmed, NEJM, as well as other esteemed peer-reviewed publications, and presents a disquieting narrative. These studies outline a compelling array of adverse reactions associated with COVID-19 vaccinations, thus offering a comprehensive glimpse into the potential risks and contradicting the official narrative regarding their safety profile.

This repository of research studies unearths a troubling panorama of adverse events linked to vaccination, encompassing a wide array of complications that spans a spectrum of severity and impact on human health: from cardiovascular irregularities, thrombotic occurrences, and inflammatory disorders to neurological manifestations, bleeding episodes, and organ-specific ailments.

What distinguishes these investigations is their granular exploration of adverse reactions, shedding light on the multifaceted complexities and potential health implications that might have been underreported or disregarded. Conditions such as myocarditis, thrombocytopenia, vasculitis, Guillain-Barré Syndrome, immune-mediated hepatitis, acute kidney injuries, and others emerge as notable concerns within the findings, including death.

Collectively, these studies underscore a troubling reality of apparent underreporting or downplaying of adverse reactions, possibly to align with a narrative that these investigations challenge. The implications are substantial, raising critical questions about the integrity of reporting mechanisms and the transparency of information relayed to the public regarding vaccine safety.

The depth and breadth of these research studies paint a concerning picture, emphasizing the imperative for thorough and transparent reporting of adverse vaccine reactions. This assortment of diverse scientific inquiries calls for a sober reassessment of the proclaimed safety and necessity of these novel vaccinations, demanding a renewed emphasis on ensuring public health and informed decision-making.

Cardiovascular and Heart-Related Disorders

Thrombosis	The formation of a blood clot within a blood vessel, which can block blood flow and lead to various health issues, including stroke or heart attack.
Thrombophilia	A tendency to develop blood clots due to an abnormality in the blood's clotting system. It increases the risk of thrombosis.
Cerebral Venous Thrombosis	The presence of blood clots in the cerebral veins, which can obstruct blood flow from the brain and cause a range of neurological symptoms.
Thrombotic Thrombocytopenic Purpura	A rare blood disorder characterized by the formation of small blood clots throughout the body, leading to a low platelet count and potentially severe complications.
Thrombocytopenia	A condition where the blood has a lower than normal number of platelets, which can lead to bleeding and easy bruising.
Myocarditis	An inflammation of the heart muscle (myocardium), which can weaken the heart and lead to serious cardiac issues.
Pericarditis	The inflammation of the pericardium, a protective sac around the heart. It can cause chest pain and affect heart function.
Myopericarditis	A condition involving both heart muscle (myocardium) and pericardial inflammation, potentially leading to more severe cardiac complications.
Perimyocarditis	A term sometimes used to describe inflammation in the area surrounding the heart muscle, which may affect heart function.

VACCINE-INDUCED IMMUNE THROMBOTIC THROMBOCYTOPENIA AND CEREBRAL VENOUS SINUS THROMBOSIS POST COVID-19 VACCINATION; A SYSTEMATIC REVIEW

SOURCE: https://www.sciencedirect.com/science/article/pii/S0022510X21003014

Abstract

The common reported adverse effects of COVID-19 vaccination consist of the injection site's local reaction followed by several non-specific flu-like symptoms. However, rare cases of vaccine-induced immune thrombotic thrombocytopenia (VITT) and cerebral venous sinus thrombosis (CVST) after viral vector vaccines (ChAdOx1 nCoV-19 vaccine, Ad26.COV2 vaccine) have been reported. Herein we systemically reviewed the reported cases of CVST and VITT following the COVID-19 vaccination.

Results

Until May 19, we found 877 articles with the searched terms. We found 12 articles, which overall present clinical features of 36 patients with CVST and VITT after the ChAdOx1 nCoV-19 vaccine. Moreover, two articles were noted, which present 13 patients with CVST and VITT after Ad26.COV2 vaccine. The majority of the patients were females. Symptom onset occurred within one week after the first dose of vaccination (Range 4–19 days). Headache was the most common presenting symptom. Intracerebral hemorrhage (ICH) and/or Subarachnoid hemorrhage (SAH) were reported in 49% of the patients. The platelet count of the patients was between 5 and 127 cells×109/l, PF4 IgG Assay and d-Dimer were positive in the majority of the reported cases. Among 49 patients with CVST, at least 19 patients died (39%) due to complications of CVST and VITT.

Conclusion

Health care providers should be familiar with the clinical presentations, pathophysiology, diagnostic criteria, and management consideration of this rare but severe and potentially fatal complication of the COVID-19 vaccination. Early diagnosis and quick initiation of the treatment may help to provide patients with a more favorable neurological outcome.

MALIGNANT CEREBRAL INFARCTION AFTER CHADOX1 NCOV-19 VACCINATION: A CATASTROPHIC VARIANT OF VACCINE-INDUCED IMMUNE THROMBOTIC THROMBOCYTOPENIA

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8329262/

Abstract

Vaccine-induced thrombotic thrombocytopenia with cerebral venous thrombosis is a syndrome recently described in young adults within two weeks from the first dose of the ChAdOx1 nCoV-19 vaccine. Here we report two cases of malignant middle cerebral artery (MCA) infarct and thrombocytopenia 9-10 days following ChAdOx1 nCoV-19 vaccination. The two cases arrived in our facility around the same time but from different geographical areas, potentially excluding epidemiological links; meanwhile, no abnormality was found in the respective vaccine batches. Patient 1 was a 57-year-old woman who underwent decompressive craniectomy despite two prior, successful mechanical thrombectomies. Patient 2 was a 55-year-old woman who developed a fatal bilateral malignant MCA infarct. Both patients manifested pulmonary and portal vein thrombosis and high level of antibodies to platelet factor 4-polyanion complexes. None of the patients had ever received heparin in the past before stroke onset. Our observations of rare arterial thrombosis may contribute to assessment of possible adverse effects associated with COVID-19 vaccination.

Discussion

In conclusion, our two cases of young adult women with massive brain artery thrombosis in addition to extensive systemic venous thrombosis, thrombocytopenia, and PF4–polyanion antibodies, developed within 10 days from ChAdOx1 nCov-19 vaccination, might represent a stroke variant of the recently named VITT syndrome. Ischemic stroke may be the first serious symptom of VITT. Physicians should be aware of this possibility and should carefully investigate patient medical history asking for any previous vaccination (within 4–28 days) especially in young female stroke patients. If low platelet count would be present (it could also be mild initially), a chest and abdominal CT scan should be performed to rule out venous thrombosis, together with an anti-PF4/heparin IgG enzyme immunoassay and functional platelet assay. If diagnosis of VITT is confirmed (but also if the suspect of VITT is high, without waiting for specific tests), non-heparin anticoagulation should be promptly started, if platelet count is up to 50 × 109/L, as well as therapy with high dose of steroids and IVIG. Platelet transfusion should be avoided.

SEVERE IMMUNE THROMBOCYTOPENIC PURPURA AFTER SARS-COV-2 VACCINE

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8565691/

Abstract

Immune thrombocytopenic purpura (ITP) is a rare hematologic condition through to affect 3.3 in 100,000 adults per year in the United States. Many cases of immune thrombocytopenia are diagnosed incidentally with laboratory tests that reveal low platelet count, without a clear cause. However, when platelet counts are very low, patients may show signs of bleeding. Here we present the case of a 24-year-old female with mucocutaneous bleeding ten days after receiving her first dose of SARS-CoV-2 vaccine, who was subsequently found to have severe thrombocytopenia. Extensive work up for new thrombocytopenia was unremarkable suggesting a diagnosis of ITP, potentially secondary to vaccination. Empiric treatment with glucocorticoids was initiated without response prompting the use of intravenous immunoglobulin G. The patient was discharged on hospital day five with a platelet count over 20,000 platelets per microliter. In summary, ITP is a potential sequela of the SARS-CoV-2 vaccine, and otherwise healthy young individuals may be at risk for hematologic side effects.

Discussions

Here we present the case of severe isolated thrombocytopenia in an otherwise healthy young adult 10 days after vaccination for SARS2-Coronavirus. The patient's platelet count was non-responsive to steroids alone, however responded to intravenous immunoglobulin. Our work up was negative for platelet-destructive medications, infection, or underlying autoimmune conditions. The onset of thrombocytopenia in our patient suggests relation to the vaccine, and thus newly diagnosed secondary ITP.

Multiple vaccines have been implicated in ITP. Vaccinations rely on an intact immune response, and thus any vaccination can trigger the disease. The mechanism by which messenger RNA vaccines may cause autoimmunity is not fully understood but is thought to involve processes like molecular mimicry and bystander activation. While in most cases ITP has an insidious onset in adults, post-vaccination ITP is thought to occur within six weeks of vaccination. In the extreme, there are cases of post-vaccination ITP reported in adults as few as four days post vaccination.

Few serious side effects have been linked to the coronavirus vaccines to date. However, cases of post-coronavirus vaccination ITP have been begun emerging in the literature. It is important to note, most have been in the setting of previous disease or published without case details. In one case, a 22-year-old male was found to have new onset thrombocytopenia after the vaccine but was subsequently found to have an elevated Sjogren's antibody.

It is interesting to note that this patient has a history of atopy and a previous local immune reaction. This immune reaction was limited to a raised red circle on her arm that was self-limited and not associated with changes to blood count. However, a history of previous reactions to vaccines may mark an increased risk of later adverse reactions. A strength of this case is the thorough immunologic and infectious work up completed, as well as the patient's response to standard therapy. Conversely, a weakness in this case is that the gold standard diagnosis of ITP is a bone marrow biopsy, which was not done for our patient given her recovery.

Conclusions

Overall, our case brings attention to potential sequalae of vaccination for SARS-2 Coronavirus. More work should be done to identify risk factors for this complication, and additional cases will be needed to establish the prognosis and to substantiate the optimal therapeutic approach.

THROMBOTIC THROMBOCYTOPENIC PURPURA AFTER AD26.COV2-S VACCINATION

SOURCE: https://pubmed.ncbi.nlm.nih.gov/33980419/

Abstract

The U.S. Food and Drug Administration (FDA) recently issued an Emergency Use Authorization (EUA) for two highly effective Sars-CoV-2 (COVID-19) vaccines from Pfizer-BioNTech and Moderna. More recently, EUA was granted for the Johnson and Johnson COVID-19 vaccine which uses traditional virus-based technology. In this vaccine, researchers added the gene for the coronavirus spike protein to modified Adenovirus 26 and named it Ad26.COV2-S. Nearly 7 million doses of the Ad26.COV2-S have been administered as of mid-April 2021. Recently the Federal Drug Administration and Center for Disease Control and Prevention reviewed data involving six reported cases in the United States of cerebral venous sinus thrombosis in combination with thrombocytopenia in people who received the vaccination. All cases were in women between 18 and 48, with symptoms developing six to 13 days after vaccination. A recent study in the United Kingdom reported similar events in 23 patients age 21 to 77, 61% of which were female, with cases of presumed vaccine induced thrombosis and thrombocytopenia occurring six to 24 days after vaccination. We report a 62-year-old female who presented to the emergency department (ED) with acute onset of altered mental status. She had received the Ad26.COV2-S vaccine 37 days prior to ED presentation. She developed thrombotic thrombocytopenic purpura (TTP) and no other cause was found. To our knowledge this is the first case in the United States of thrombotic thrombocytopenic purpura after receiving the Ad26.COV2-S COVID-19 vaccine.

(...)

Another vaccine approved for emergency use authorization, the BioNTech ChAdOx1 nCoV-19 vaccine, also uses adenovirus based technology and has been correlated with a pathogenic PF4-dependent syndrome, unrelated to the use of heparin therapy, called VITT [[2],,]. In almost every patient, high levels of antibodies to platelet factor 4 (PF4)–polyanion complexes were identified by enzyme-linked immunosorbent assay (ELISA), as well by assays based on platelet activation, which, when tested, was enhanced by addition of PF4. In contrast to heparin-induced thrombocytopenia, binding of antibody to PF4 occurred in the absence of heparin. This serologic pattern mirrors findings in patients with “atypical” or “autoimmune” heparin-induced thrombocytopenia, in whom thrombi develop in the absence of known previous exposure to heparin, but the distribution of thrombi in patients with that condition clearly differs from that in patients with VITT. In VITT, the majority of cases of thrombosis are in the cerebral veins. On the basis of these reports, the diagnosis of VITT should be confirmed with an approved P4 ELISA. Our patient was PF4 negative.

This patient's TTP was likely caused by her recent vaccination with Ad26.COV2-S, as no other cause could be definitively determined. However, the mechanism for this is currently unknown. We hope this case provides information on the potential clinical presentation, laboratory findings and treatment in patients with TTP who were recently vaccinated with Ad26.COV2-S vaccine.

THROMBOTIC THROMBOCYTOPENIC PURPURA: A NEW MENACE AFTER COVID BNT162B2 VACCINE

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8280631/

Abstract

Thrombotic thrombocytopenic purpura (TTP) is a known menace in hematology and is quite rare in practice with known triggers. Lately, in the COVID-19 pandemic, hematology has seen a new pathology amongst which TTP associated with COVID-19 messenger RNA (mRNA) vaccine is unique. We report a case of a 69-year-old male with multiple comorbidities who presented to the hospital with severe fatigue and shortness of breath. Labs were significant for thrombocytopenia, anemia, and hemolysis with schistocytes consistent with TTP with a second dose of BNT162b2 mRNA vaccine as a likely culprit been documented.

Discussion

Reports on Ad26.COV2.S vaccine reported symptoms like bilateral lower leg edema and shortness of breath, along with thrombotic thrombocytopenic events in women aged less than 60 years.

Yocum and Sissa reported women with co-morbidities in a similar age group as our patient presenting with similar symptoms within a month of administration of the Ad26.COV2.S and BNT162b2 mRNA vaccines, respectively, indicating the presence of a possible diagnosis of VIPIT that was treated efficiently with plasmapheresis in both cases. Of note, in the latter case involving BNT162b2, the patient suffered from relapse precisely six days after the second dosage of COVID vaccine, just as in our case—although our patient never had TTP before. TTP is commonly treated with plasmapheresis, chemotherapeutics, for example, vincristine and corticosteroids with splenectomy kept as a last resort in case of refractory disease.

Further studies are, however, needed to verify possible associations between microangiopathic, thrombocytopenic thrombotic disorders and the administration of vaccines against COVID-19, so the menace can be nipped in the bud before the presumptive rewarding efforts go in vain.

COVID-19 VACCINE-ASSOCIATED ACUTE CEREBRAL VENOUS THROMBOSIS AND PULMONARY ARTERY EMBOLISM

SOURCE: https://academic.oup.com/qjmed/article/114/7/506/6319032?login=false

Introduction

Coronavirus disease 2019 (COVID-19) is still an ongoing pandemic, caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). However, the administration of vaccines against SARS-CoV-2 has resulted in reports of adverse events after vaccination in worldwide. Several cases of thrombotic events and thrombocytopenia developed after receiving the first dose of ChAdOx1 nCoV-19 (AstraZeneca) vaccine. Including cerebral venous sinus thrombosis, pulmonary embolus, and deep vein thrombosis have been reported recently.1–3 The reaction is mediated by platelet-activating antibodies against platelet factor 4 (PF4), which clinically mimics autoimmune heparin-induced thrombocytopenia.

Discussion

Thrombocytopenia and thrombotic complications at unusual sites may develop around 1–2 weeks after the first vaccine dose of ChAdOx1 nCov-19. The incidence is still not well-known but it appears to be extremely rare. Clinicians should be aware that a syndrome similar to autoimmune heparin-induced thrombocytopenia may occur in very few persons after exposure to the ChAdOx1 nCoV-19 vaccines. However, these vaccinated patients did not receive any heparin to explain the subsequent occurrence of thrombosis and thrombocytopenia. In all cases reported to date, this syndrome of thrombocytopenia and venous thrombosis appears to be triggered by receipt of the first dose of the vaccine. The pathomechanism is presumably the formation of antibodies against PF4, causing platelet consumption with thrombocytopenia and thrombus formation. Whether these anti-PF4 autoantibodies induced by the strong inflammatory stimulus of vaccination or caused by the vaccine that cross-react with PF4 and platelets requires further investigation. Administration of high-dose intravenous immunoglobulin (1 g/kg daily for 2 days) or dexamethasone (40 mg days for 4 days) may be useful to interrupt the prothrombotic mechanism. Use of direct oral anticoagulants is also suggested. In these patients, platelet transfusions should not be transfused in the absence of bleeding. Anticoagulation with unfractionated heparin or low molecular weight heparin should be avoided.

In conclusion, COVID-19 vaccine-associated immune thrombosis and thrombocytopenia is a phenomenon with devastating effects for otherwise healthy young adults and requires a thorough risk–benefit analysis. Clinicians should be aware of these associated complications, the early recognition and well-timed treatment can improve clinical outcomes.

SARS-COV-2 VACCINE-INDUCED CEREBRAL VENOUS THROMBOSIS

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8148433/

Abstract

The nosological entity of the cerebral venous thrombosis caused by the SARS-CoV-2 vaccination differs from the common cerebral venous thrombosis in that it is due to immune thrombocytopenia triggered by vaccination. Cerebral venous thrombosis is one of several manifestations of this type of immune thrombocytopenia. Albeit many general aspects of management of cerebral venous thrombosis are similar, immune thrombocytopenia requires a specific therapeutic approach, which is not normally adopted for cerebral venous thrombosis due to other causes, therefore its early recognition is essential.

Conclusions

CVT after SARS-CoV-2 vaccination can be the first manifestation of a much more complex and life-threatening disorder, mimicking heparin-induced thrombocytopenia. CVT is not the only manifestation of vaccine-induced immune thrombotic thrombocytopenia, which can also occur with thrombosis in other sites. It is necessary to pay close attention to the most common thrombotic manifestations, such as stroke and myocardial infarction, among subjects with risk factors, because it cannot be excluded that some of these cases are adverse effects of the vaccine.

A headache, which is also a frequent symptom after vaccination, could be a manifestation of a CVT in a vaccine-induced immune thrombotic thrombocytopenia and a simple platelet count could help rule out this form. Conversely, a thrombocytopenia in patients with thrombotic manifestations of any kind within 4 weeks of vaccination (all cases reported so far have occurred within 24 days of vaccination[8],,), should lead to a search for anti-FP4 antibodies.

A well-rounded awareness of these events' clinical and laboratory features plays a crucial role in the early identification of patients at their first clinical manifestation and helps undertake all preventions to avoid the dramatic consequences of immune thrombocytopenia. Although the indications on the treatment of vaccine-induced immune thrombotic thrombocytopenia are derived from studies on thrombocytopenia induced by heparin, the widespread knowledge of this possible severe adverse event of SARS-CoV-2 vaccination is already a good starting point.

OXFORD-ASTRAZENECA COVID-19 VACCINE-INDUCED CEREBRAL VENOUS THROMBOSIS AND THROMBOCYTOPAENIA: A MISSED OPPORTUNITY FOR A RAPID RETURN OF EXPERIENCE

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8141689/

Introduction

Oxford-AstraZeneca COVID-19 vaccination started In France the 6th of February 2021, with 3.7 million doses being administered on the 25th of April 2021. The 21st and 23rd of March 2021, we had to manage in the ICU two patients with severe cerebral venous thrombosis associated with thrombocytopaenia in the context of recent vaccination. Progressive severe disorders of consciousness developed and decompressive craniectomy was performed in both patients.

We were aware of the possibility of cerebral venous thrombosis after COVID-19 vaccination, and the declaration to our regional pharmacovigilance centre was made on the 23rd of March 2021. We would like, however, to share the difficulties we had to find reliable clinical information in this context.

Conclusions

We propose that, in the case of serious and life-threatening conditions, pharmacovigilance agencies, in addition to collecting and analysing serious events, should propose the possibility of a rapid contact between clinicians who have reported similar events via an exchange of e-mail addresses or the creation of discussion forums, on a global and international scale. As publication process for original articles and guidelines requires several weeks, this rapid feedback and sharing of information seem essential in such situations with new, serious, life-threatening and potentially frequent adverse events, for which the scientific knowledge and clinical experience are very limited.

US CASE REPORTS OF CEREBRAL VENOUS SINUS THROMBOSIS WITH THROMBOCYTOPENIA AFTER AD26.COV2.S VACCINATION, MARCH 2 TO APRIL 21, 2021

SOURCE: https://pubmed.ncbi.nlm.nih.gov/33929487/

Abstract

Importance: Cerebral venous sinus thrombosis (CVST) with thrombocytopenia, a rare and serious condition, has been described in Europe following receipt of the ChAdOx1 nCoV-19 vaccine (Oxford/AstraZeneca), which uses a chimpanzee adenoviral vector. A mechanism similar to autoimmune heparin-induced thrombocytopenia (HIT) has been proposed. In the US, the Ad26.COV2.S COVID-19 vaccine (Janssen/Johnson & Johnson), which uses a human adenoviral vector, received Emergency Use Authorization (EUA) on February 27, 2021. By April 12, 2021, approximately 7 million Ad26.COV2.S vaccine doses had been given in the US, and 6 cases of CVST with thrombocytopenia had been identified among the recipients, resulting in a temporary national pause in vaccination with this product on April 13, 2021.

Results

Patients' ages ranged from 18 to younger than 60 years; all were White women, reported from 11 states. Seven patients had at least 1 CVST risk factor, including obesity (n = 6), hypothyroidism (n = 1), and oral contraceptive use (n = 1); none had documented prior heparin exposure. Time from Ad26.COV2.S vaccination to symptom onset ranged from 6 to 15 days. Eleven patients initially presented with headache; 1 patient initially presented with back pain and later developed headache. Of the 12 patients with CVST, 7 also had intracerebral hemorrhage; 8 had non-CVST thromboses. After diagnosis of CVST, 6 patients initially received heparin treatment. Platelet nadir ranged from 9 ×103/μL to 127 ×103/μL. All 11 patients tested for the heparin-platelet factor 4 HIT antibody by enzyme-linked immunosorbent assay (ELISA) screening had positive results. All patients were hospitalized (10 in an intensive care unit [ICU]). As of April 21, 2021, outcomes were death (n = 3), continued ICU care (n = 3), continued non-ICU hospitalization (n = 2), and discharged home (n = 4).

Conclusions and relevance

The initial 12 US cases of CVST with thrombocytopenia after Ad26.COV2.S vaccination represent serious events. This case series may inform clinical guidance as Ad26.COV2.S vaccination resumes in the US as well as investigations into the potential relationship between Ad26.COV2.S vaccine and CVST with thrombocytopenia.

DIAGNOSTIC AND TREATMENT RECOMMENDATIONS FROM THE FACME AD-HOC EXPERT WORKING GROUP ON THE MANAGEMENT OF CEREBRAL VENOUS SINUS THROMBOSIS ASSOCIATED WITH COVID-19 VACCINATION

SOURCE: https://www.sciencedirect.com/science/article/pii/S0213485321000839

Abstract

Introduction
Cases of cerebral venous sinus thrombosis have been reported in individuals vaccinated against COVID-19 with non-replicating adenoviral vector vaccines. We issue our recommendations on the diagnosis and management of patients presenting this complication.

Results

We define suspected cases as those cases of cerebral venous sinus thrombosis occurring between 3 and 21 days after the administration of non-replicating adenoviral vector vaccines, in patients with a platelet count below 150,000/µL or presenting a decrease of 50% with respect to the previous value. Findings suggestive of vaccine-induced immune thrombotic thrombocytopaenia include the presence of antibodies to platelet factor 4, D-dimer levels 4 times greater than the upper limit of normal, and unexplained thrombosis. The recommended treatment includes intravenous administration of non-specific human immunoglobulin or alternatively plasmapheresis, avoiding the use of heparin, instead employing argatroban, bivalirudin, fondaparinux, rivaroxaban, or apixaban for anticoagulation, and avoiding platelet transfusion.

Conclusions

Non-replicating adenoviral vector vaccines may be associated with cerebral venous sinus thrombosis with thrombocytopaenia; it is important to treat the dysimmune phenomenon and the cerebral venous sinus thrombosis.

THROMBOSIS AND THROMBOCYTOPENIA AFTER CHADOX1 NCOV-19 VACCINATION

SOURCE: https://www.nejm.org/doi/full/10.1056/NEJMoa2104882

Discussion

Our findings indicate a shared pathophysiological basis of the condition in these five patients and should raise awareness that a syndrome similar to autoimmune heparin-induced thrombocytopenia may occur in some persons after vaccination with ChAdOx1 nCoV-19. By providing a link between thrombosis and the immune system, these results strengthen the view that vaccination may have triggered the syndrome.

In these cases, the characteristic antibodies were first identified after the initiation of anticoagulation treatment with low-molecular-weight heparin for life-threatening thrombosis and thrombocytopenia (Figure 1). With the antibody results in hand, the clinicians faced the dilemma of deciding which anticoagulant to administer during this syndrome, which is usually associated with heparin. However, platelet counts were increasing after concomitant treatment with intravenous immune globulin and prednisolone had been initiated, and no clinical evidence suggested that thrombosis was increasing. Moreover, there were significant concerns that administration of anticoagulation alternatives to heparin or low-molecular-weight heparin might lead to aggravation of the ongoing intracerebral hemorrhage. Fondaparinux has a longer half-life than low-molecular-weight heparin, and a well-documented reversal strategy for factor Xa inhibitors is not available. It is worth noting that platelet counts continued to increase in all the patients despite continuation of treatment with low-molecular-weight heparin (Figure 1). This finding may reflect the efficacy of early treatment with intravenous immune globulin, which has proved to be highly effective against spontaneous heparin-induced thrombocytopenia.

Treating severely ill patients such as those described in this report is always challenging. The most important implication of our findings is that physicians should have a low threshold for requesting ELISA testing for PF4–polyanion antibodies, including confirmatory functional testing, in patients who have unexpected symptoms after vaccination.

Although rare, VITT is a new phenomenon with devastating effects for otherwise healthy young adults and requires a thorough risk–benefit analysis. The findings of our study indicate that VITT may be more frequent than has been found in previous studies in which the safety of the ChAdOx1 nCoV-19 vaccine has been investigated

THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME ASSOCIATED WITH COVID-19 VACCINES

SOURCE: https://www.sciencedirect.com/science/article/pii/S0735675721004381

Discussion

TTS, also known as vaccine-induced immune thrombotic thrombocytopenia, is a reaction associated with exposure to the ChAdOx1 nCoV-19 (Oxford-AstraZeneca) and AD26.COV2·S (Johnson & Johnson) vaccine, which may result in thrombocytopenia and thrombotic events. There are several case series of patients diagnosed with TTS, but the overall incidence is rare. TTS is characterized by exposure to one of the aforementioned vaccines 4–30 days prior to presentation, followed by thrombosis, mild-to-severe thrombocytopenia, and a positive platelet factor-4 (PF4)-heparin enzyme-linked immunosorbent assay (ELISA). Thrombosis typically involves atypical locations, including cerebral venous thrombosis and splanchnic vein thrombosis. Evaluation should include complete blood count, peripheral smear, D-dimer, fibrinogen, coagulation panel, renal and liver function, and electrolytes, as well as PF4-heparin ELISA if available. Consultation with hematology is recommended if suspected or confirmed. Treatment may include intravenous immunoglobulin and anticoagulation, while avoiding heparin-based agents and platelet transfusion.

Conclusions

With increasing vaccine distribution, it is essential for emergency clinicians to be aware of the evaluation and management of this condition.

VACCINE-ASSOCIATED THROMBOCYTOPENIA AND THROMBOSIS: VENOUS ENDOTHELIOPATHY LEADING TO VENOUS COMBINED MICRO-MACROTHROMBOSIS

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8621006/

“Special Note” on TTP-Like Syndrome and ADAMTS13 after COVID-19 Vaccines

In the pre-COVID-19 pandemic era, only a handful of cases of TTP-like syndrome had been recorded following vaccination. Questionable cases of vaccine-associated TTP-like syndrome or relapsed TTP have been reported. To the best of our knowledge well-documented case of de novo TTP after vaccination has not been documented after COVID-19 vaccines, but latest two cases of TTP-like syndrome after COVID-19 vaccine may support the relationship between COVID-19 vaccine and arterial endotheliopathy. Since TTP-like syndrome (aEA-VMTD), which has often been associated with ADAMTS13 insufficiency and arterial endotheliopathy, it is possible that additional components of vaccines such as surfactants or adjuvants in vaccines might cause some effects on the arterial system via complement activation. In both aEA-VMTD and vEA-VMTD, ADAMTS13 insufficiency is a thrombophilic condition via the activated ULVWF path due to its heterozygous gene mutation/polymorphism or imbalanced/relative deficiency caused by excessive exocytosis of ULVWF multimers in endotheliopathy. Therefore, in patient care and vaccine development, the medical community should be vigilant with the close monitoring of TTP-like syndrome and ITP-like syndrome and evaluate the role of ADAMTS13 for the diagnostic use and therapeutic potential.

Conclusions

The pathogenesis of vaccine-associated thrombocytopenia is characterized by venous endotheliopathy promoting microthrombosis and platelet consumption (ITP-like syndrome) triggered by an activated complement system due to inactivated pathogen/toxin/viral molecule and/or adjuvant conjugated with vaccine. When venous microthrombosis of vEA-VMTD encounters fibrin meshes from an activated TF path following vaccine-unrelated vascular injury, VTE or CVST occurs as a result of the unifying mechanism of microthrombi and fibrin meshes, leading to venous combined micro-macrothrombosis. The clinical hemostatic disorders and inflammatory syndromes are consistent with attenuated sepsis-like syndrome. Fortunately, arterial endotheliopathy has not been a major issue after COVID-19 vaccination.

POSSIBLE RISK OF THROMBOTIC EVENTS FOLLOWING OXFORD-ASTRAZENECA COVID-19 VACCINATION IN WOMEN RECEIVING ESTROGEN

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8560237/

Abstract

People who receive the ChAdOx1 nCoV-19 vaccine, particularly perimenopausal women who are on birth control or postmenopausal women who take estrogen supplements, may experience thrombosis and thrombocytopenia. Estrogen and the ChAdOx1 nCoV-19 vaccine both have the potential to cause thrombus in different ways. Some postmenopausal women who are also taking estrogens may develop thrombosis and thrombocytopenia after receiving the ChAdOx1 nCoV-19 vaccine. Therefore, women are encouraged to stop taking drugs containing estrogen before receiving this vaccine. Furthermore, consuming fish oil can help reduce the risk of developing blood clots among women who are in the luteal phase and, thus, have high estrogen levels. In addition, ChAdOx1 nCoV-19's side effects in young women could be mitigated by administering it during the follicular phase.

Conclusion

Postmenopausal women who received estrogen-containing drugs may be prone to developing thrombosis and thrombocytopenia after being inoculated with the Oxford-AstraZeneca vaccine. Therefore, this vaccine should be administered to such women with great caution. It is strongly recommended that women who take estrogen-containing oral contraceptives discontinue use before receiving the Oxford-AstraZeneca vaccine. These women are also encouraged to consume fish oil before being vaccinated, as this can reduce the risk of clots. To further reduce the risk of thrombosis and thrombocytopenia, women should plan to receive this vaccine during the follicular phase of the menstrual cycle.

IMMUNE THROMBOCYTOPENIA ASSOCIATED WITH PFIZER-BIONTECH'S BNT162B2 MRNA COVID-19 VACCINE

SOURCE: https://www.sciencedirect.com/science/article/pii/S2214250921002018

Abstract

The recent global pandemic of coronavirus disease 2019 (COVID-19) has led to vaccination in many parts of the world for herd immunity, and as vaccination has progressed, several rare adverse events have been reported. Immune thrombocytopenia (ITP) has been reported to be one of the rare adverse events caused by vaccination with MMR (measles-mumps-rubella) vaccine and influenza vaccine. In addition, ITP has been reported to occur in a small number of cases associated with the COVID-19 messenger ribonucleic acid (mRNA) vaccine. However, there are few reports on the details of the treatment and clinical course; optimal treatment has not yet been established. We report the case of a 20-year-old woman who developed ITP after receiving Pfizer-BioNTech's BNT162b2 vaccine. She had generalized subcutaneous hemorrhage, 14 days after vaccination. At the time of our visit, she had marked thrombocytopenia and intraoral bleeding; she was diagnosed with ITP. Treatment with oral steroids was started and the platelet count promptly improved after 4 days of treatment. Since the response to treatment was very good, we tapered off the steroids. As these vaccines will be increasingly used in the future, it is important to recognize ITP as a possible adverse event.

Discussion

As of June 24, 2021, a total of 23 cases of newly diagnosed ITP have been reported after administration of the COVID-19 Pfizer-BioNTech's BNT162b2 and Moderna's mRNA-1273 vaccines [[4],,,,,,]. It is impossible to strictly distinguish between vaccine-induced secondary ITP and incidental primary ITP that occurred soon after vaccination. However, of the cases identified so far, 22 occurred after the first vaccination and only one after the second vaccination. Since the frequencies of occurrence are highly uneven, there is likely to be a causal relationship between the COVID-19 vaccine and the development of ITP. Lee et al. also reported that symptoms of bleeding occurred between 1 and 23 days (median 5 days) after vaccine administration. In the present case, bleeding symptoms occurred 14 days after the first dose of the vaccine, which is consistent with a previously reported course.

ITP has been reported to be associated with various vaccinations such as the MMR vaccine, influenza vaccine, and polio vaccine. The pathogenesis is presumed to be immune-mediated and is thought to be related to the increased B-cell function seen in primary ITP [12,13]. Since mRNA vaccines have a different mode of action from conventional vaccines, it is unclear what mechanism causes the immune-mediated reaction. However, many patients, including the patient in this report, responded well to immunosuppressive therapy, suggesting that an immune-mediated mechanism may be involved.

In this case, we administered 1 mg/kg of prednisolone as initial treatment as with primary ITP. The platelet count recovered to the reference level within a short period of 4 days. We assumed that this was vaccine-induced secondary ITP and rapidly reduced the dose. We avoided long-term steroid administration, as recommended for primary ITP. The platelet count remained normal after dose reduction.

We encountered an extremely rare case of secondary ITP presumed to have occurred after BNT162b2 vaccination. Secondary ITP being a very rare complication, the optimal treatment has not yet been determined, and further case series will be necessary. On the other hand, the incidence of symptomatic thrombocytopenia after vaccination is much lower than the risk of death and morbidity due to SARS-CoV-2 infection, as stated in the Medical Advisory Board statement on the Platelet Disorder Support Association website. The purpose of this case report is not to diminish the usefulness of vaccination or the well-documented safety profile of Pfizer-BioNTech's BNT16B2b2 mRNA vaccine.

PRIMARY ADRENAL INSUFFICIENCY ASSOCIATED WITH OXFORD-ASTRAZENECA CHADOX1 NCOV-19 VACCINE-INDUCED IMMUNE THROMBOTIC THROMBOCYTOPENIA (VITT)

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8271354/

Findings

In the setting of coronavirus disease 2019 (COVID-19) vaccination a very uncommon cause for adrenal insufficiency was observed in a 47-year-old man without previous relevant disease who was admitted for bilateral segmentary pulmonary embolism (without hemodynamic compromise) 10 days after receiving adenoviral (ChAdOx1) vector-based COVID-19 vaccine. Therapy with low-molecular-weight-heparin (LMWH) was initiated and 24 h later the patient began to develop neurological symptoms (headache, somnolence, and mild confusion). Physical examination showed normal vital signs (blood pressure: 139/93 mmHg, pulse-oxygen saturation: 96%, afebrile), slow mental activity, negative meningeal signs, and absence of focal neurological deficit. Laboratory tests showed a substantial increase in d-dimer (20,506 ng/ml) and thrombocytopenia (51,000/µl; previous: 103,000/µl) as main findings. In cranial CT/MRI, findings of cerebral venous thrombosis were detected in several locations (Fig. 1a and 1b). With clinical diagnosis of vaccine-induced immune thrombotic thrombocytopenia (VITT), LMWH was discontinued and treatment with intravenous immunoglobulins and subcutaneous fondaparinux was started. Platelet-factor-4 (PF4) antibody testing was positive. Ten days later, the patient had a completely normal level of consciousness and mental status, and control cranial MRI was performed (Fig. 2), showing partial revascularization of the superior sagittal cerebral venous sinus. However, he started to develop arterial hypotensive tendency and progressive abdominal discomfort. Mild hyponatremia was detected (natraemia:130 mmol/L; previous levels: 138–140 mmol/L). Abdominal MR image showed bilateral adrenal nodular enlargement with hyperintense peripheral halo and hypointense center, corresponding to ongoing subacute bilateral adrenal hemorrhage (Fig. 3). In hormonal laboratory testing, low levels of cortisol (3.8µg/dL; range values:4.8–19.5), DHEA (0.3 ng/mL;1.1–10.6 ng/mL) and aldosterone (42.2pg/mL;70–300), and high ACTH levels (345 pg/mL;7–63) confirmed primary adrenal insufficiency. Hormone replacement therapy with hydrocortisone was started, achieving disappearance of abdominal pain and rapid normalization of natraemia levels. Finally, the patient was discharged with the diagnosis of non-massive pulmonary embolism, cerebral venous thrombosis and primary adrenal insufficiency due to bilateral adrenal hemorrhage in the setting of vaccine-induced immune thrombotic thrombocytopenia (VITT).

Adrenal insufficiency is an infrequent entity, mainly caused by autoimmune adrenalitis (up to 90% of the cases). Among the remaining etiologies, bilateral adrenal hemorrhage has been described in association with heparin-induced thrombocytopenia and, more recently, with sporadic cases of ChAdOx1 nCoV-19 vaccine-induced immune thrombotic thrombocytopenia (VITT) [2,3], as expression of thrombosis in unusual sites including cerebral, splanchnic and adrenal veins. However, symptomatic adrenal insufficiency has rarely been described.

VITT is caused by antibodies that recognize platelet factor 4 and induce platelet activation with a significant stimulation of the coagulation system, leading to clinically relevant thromboembolic events [4, 5, 6]. In this setting, when thrombosis affects adrenal veins, an adrenal hemorrhagic infarction develops, and in bilateral involvement, adrenal insufficiency may be clinically manifested. Nevertheless, in large population-based cohorts and randomized clinical trials reporting cardiovascular and hemostatic events with Oxford-AstraZeneca ChAdOx1 nCoV-19 [7, 8], adrenal bleeding has scarcely been described and adrenal insufficiency has not been reported.

Clinical manifestations of adrenal insufficiency are nonspecific and include fatigue, gastrointestinal complaints (nausea, vomiting, abdominal pain) and postural hypotension, while most common laboratory findings include hyponatremia and hyperkalemia. In cases of intercurrent severe stress an adrenal crisis (entity associated with high lethality) may be precipitated.

In conclusion, due to its nonspecific clinical manifestations and its potentially fatal course, it is very important to have a high index of suspicion for adrenal insufficiency in the setting of hypercoagulable states such as vaccine-induced immune thrombotic thrombocytopenia.

AGE- AND SEX-SPECIFIC INCIDENCE OF CEREBRAL VENOUS SINUS THROMBOSIS ASSOCIATED WITH AD26.COV2.S COVID-19 VACCINATION

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8561428/

Introduction

This cohort study compares the sex- and age-adjusted incidence of cerebral venous sinus thrombosis before the COVID-19 pandemic with that during the first 92 days after Ad26.COV2.S vaccination.

Recent reports1,2,3,4 suggest a possible association between Ad26.COV2.S (Johnson & Johnson/Janssen) COVID-19 vaccination and cerebral venous sinus thrombosis (CVST). Estimates of postvaccination CVST risk require accurate age- and sex-specific prepandemic CVST incidence rates; however, reported rates vary widely.5 We compared the age- and sex-specific CVST rates after Ad26.COV2.S vaccination with the prepandemic CVST rate in the population.

Discussion

In this population-based cohort study, we found that the CVST incidence rate 15 days after Ad26.COV2.S vaccination was significantly higher than the prepandemic rate. However, the higher rate of this rare adverse effect must be considered in the context of the effectiveness of the vaccine in preventing COVID-19 (absolute reduction of severe or critical COVID-19 of 940 per 100 000 PY).6

Most CVST events occurred within 15 days after vaccination, which is likely the highest at-risk period. The postvaccination CVST rate among females was higher than the prepandemic rate among females. The highest risk was among women aged 30 to 49 years, but the absolute CVST risk was still low in this group (up to 29.5 per 100 000 PY among women aged 40-49 years). The reason that women had a higher incidence of postvaccination CVST is unclear; concomitant CVST risk factors or autoantibody production might have been involved.2 The overall prepandemic CVST incidence rate was slightly higher in our study than in other studies (0.22-1.57 per 100 000 PY)5 likely because we captured all objectively diagnosed incident CVST cases in a well-defined population, including those discovered at autopsy.

The present study avoided referral bias and included only objectively diagnosed and confirmed cases. Only cases with adequate details or imaging findings reported on VAERS were used. Study limitations include possible ascertainment bias by including only objectively diagnosed CVST cases. VAERS reporting is voluntary and subject to reporting biases. VAERS monitors vaccine adverse events but does not prove causality.

BILATERAL SUPERIOR OPHTHALMIC VEIN THROMBOSIS, ISCHAEMIC STROKE, AND IMMUNE THROMBOCYTOPENIA AFTER CHADOX1 NCOV-19 VACCINATION

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8046413/

Abstract / Discussion

A 55-year-old woman presented with conjunctival congestion, retro-orbital pain, and diplopia. She had received her first vaccine against SARS-CoV-2—ChAdOx1 nCoV-19—10 days before admission. Both on the night after the vaccination and 7 days later, the patient reported marked flu-like symptoms and a fever. She had no medical history of visual problems, autoimmune disorders, stroke, thrombosis, thrombocytopenia, neurological disorders, or arterial disease risk factors—including hypertension, diabetes, or smoking. (...)

Laboratory investigations on admission showed a marked isolated thrombocytopenia of 30 × 109 per L (figure). IgG antiplatelet antibodies were positive, and IgM antiplatelet antibodies were borderline; a platelet suspension immunofluorescence test and a monoclonal antibody-specific immobilisation of platelet antigens assay were positive—supporting a diagnosis of secondary immune thrombocytopenia (ITP). IgG antibodies against platelet factor 4/polyanion complexes—tested using a lateral flow immunoassay, 4 days after starting heparinisation—were negative. Other possible causes of thrombocytopenia—including antiphospholipid syndrome, thrombotic microangiopathy, and hepatitis B virus and hepatitis C virus, HIV, cytomegalovirus, hantaviruses, and Helicobacter pylori infections—were excluded.

Because we suspected ITP, intravenous dexamethasone 40 mg daily was given for 4 days which resulted in an increasing platelet count (figure). Despite the therapeutic heparinisation, 8 days after admission, the patient developed a transient, mild, right-sided hemiparesis, and aphasia. An MRI showed an ischaemic stroke in the left parietal lobe, middle cerebral artery territory, with restricted diffusion (figure), which had not been detected in the earlier scan. The patient then developed right-sided focal seizures which were controlled with levetiracetam and lacosamide; anticoagulation was switched to phenprocoumon, and 26 days after admission, she was allowed home.

That 8, 10, and 18 days after the ChAdOx1 nCoV-19 vaccination, our previously healthy patient developed marked flu-like symptoms, two rare disorders—namely, bilateral SOVT and ITP, and an ischaemic stroke, may indicate a causal relationship. According to the European Medicines Agency review, March 18, health-care professionals should be on the alert for possible cases of thromboembolism—like cerebral venous sinus thrombosis, pulmonary embolus, and deep vein thrombosis—occurring in people who have recently received the ChAdOx1 nCoV-19 vaccine. The thrombotic events—including bilateral SOVT as seen in our patient—may occur in the context of thrombocytopenia (video).

FULMINANT MYOCARDITIS AND SYSTEMIC HYPERINFLAMMATION TEMPORALLY ASSOCIATED WITH BNT162B2 MRNA COVID-19 VACCINATION IN TWO PATIENTS

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8372420/

Abstract

Immune-mediated myocardial injury following Severe Acute Respiratory Syndrome Coronavirys-2 (SARS-CoV2) infection has been described in adults and children. Cases of myocarditis following immunization for SARS-CoV2 have recently been documented, mostly associated with mild severity and spontaneous recovery. We herein report two cases of fulminant myocarditis following BNT162b2 mRNA Covid-19 vaccination associated with systemic hyperinflammatory syndrome and refractory shock requiring support with veno-arterial extracorporeal membrane oxygenation.

Discussion

A 27-year-old male with trisomy 21 complicated by speech impairment without history of cardiovascular disease presented in cardiogenic shock 2 days after his second vaccine dose. He had received the first dose without adverse effects. Approximately 36 h after the second dose, he developed nausea and vomiting. (…) After return of circulation, he was supported by multiple vasopressors, mechanical ventilation, and renal replacement therapy (RRT). Despite these interventions, multiorgan failure and refractory shock persisted. (…) Polymerase chain reaction (PCR) for SARS-CoV2 and other common respiratory viruses more frequently associated with myocarditis was negative. SARS-CoV2 spike protein IgG antibody was positive (62.8 arbitrary units/ml [NV <15.0]), and anti-nucleocapsid IgG was negative, consistent with immunization status. Approximately 21 h after admission, patient died due to recurrent cardiac arrest and refractory shock. Family declined request for autopsy.

A 34-year-old female without prior medical history presented 9 days after her first vaccine dose. On day 4 after vaccine, she developed fevers, cough, chest pain, nausea, and vomiting. (…) PCR for SARS-CoV2 and other common respiratory viruses was negative. SARS-CoV2 spike protein IgG antibody was positive (64 arbitrary units/ml), and IgG anti-nucleocapsid was negative, consistent with immunization due to vaccine without prior infection. (…) Genetic testing for 121 genes (Invitae, San Francisco, CA, USA) showed no variants associated with genetic disorders. Guideline-directed heart failure treatment was also initiated. She was discharged from the hospital after 73 days.

In summary, both cases presented features of fulminant myocarditis with a temporal association with the BNT162b2 mRNA Covid-19 vaccination, in absence of other apparent causes, and with unique features of systemic hyperinflammation associated with refractory shock.

Several reports in the past months had suggested a possible association between the BNT162b2 mRNA Covid-19 and myocarditis, and the Center for the Disease Control (CDC) in the United States of America has now acknowledged an increased risk of myocarditis, especially in young adults. An excess in number of cases after the second injection, as compared with the first injection, in young adults has been noted. The severity of the cases reported so far have been, for the most part, rather mild. The CDC report of 12 July 2021 identified 633 reports of myocarditis and pericarditis with a very small number being critical requiring intensive care.

SARS-COV-2 VACCINATION AND MYOCARDITIS IN A NORDIC COHORT STUDY OF 23 MILLION RESIDENTS

SOURCE: https://jamanetwork.com/journals/jamacardiology/fullarticle/2791253

Introduction

Case reports, surveillance data, and other reports from the US, Israel, and Canada indicate an increased risk of myocarditis after vaccination with SARS-CoV-2 mRNA vaccines, higher after the second dose, especially in younger men. Data from Canada and France indicate more cases of myocarditis after mRNA-1273 than after BNT162b2, but this remains to be elucidated. In nationwide cohort studies in Denmark, Finland, Norway, and Sweden, we evaluated the risks of myocarditis and pericarditis following SARS-CoV-2 vaccination in a combined population of 23.1 million individuals. High-quality nationwide registers enabled us to evaluate the risk by vaccine product, vaccination dose number, sex, and age.

Results

Myocarditis and Pericarditis During Follow-up: During the 28-day risk periods following vaccination and during unvaccinated periods (13 million person-years in total), we observed 1077 incident myocarditis cases and 1149 incident pericarditis cases. Incidence rates of myocarditis during the unvaccinated period were 9.7 per 100 000 person-years for males and 4.3 per 100 000 person-years for females (Table 2). Among individuals aged 16 to 24 years, incidence rates were 18.8 per 100 000 person-years for males and 4.4 per 100 000 person-years for females. Incidence rates of pericarditis increased with age (eTable 4 in the Supplement).

Discussion

This cohort study of 23.1 million residents across 4 Nordic countries showed higher rates of myocarditis and pericarditis within 28 days after being vaccinated with SARS-CoV-2 mRNA vaccines compared with being unvaccinated. The risks of myocarditis and pericarditis were highest within the first 7 days of being vaccinated, were increased for all combinations of mRNA vaccines, and were more pronounced after the second dose. A second dose of mRNA-1273 had the highest risk of myocarditis and pericarditis, with young males aged 16 to 24 years having the highest risk. (…)

Our findings are consistent with higher risk after the second dose and higher risk in young males. Excess events within 28 days in males aged 16 to 24 years of 5.55 events per 100 000 vaccinees after the second dose with BNT162b2 and 18.39 events per 100 000 vaccinees after the second dose with mRNA-1273 are among the highest reported. Our finding of a higher risk of myocarditis after mRNA-1273 than after BNT162b2 in this group is in line with data from the US, Canada, France, and England. In comparison with previous studies, we had the advantage of data analyzed according to a common protocol from 4 different countries, and that showed similar directions of associations, despite considerable differences in prior SARS-CoV-2 infection levels and lockdown policies.

ACUTE MYOCARDITIS AFTER SARS-COV-2 VACCINATION IN A 24-YEAR-OLD MAN

SOURCE: https://www.sciencedirect.com/science/article/pii/S0870255121003243

Abstract

A 24-year old male nurse presented to the emergency department complaining of chest pain with onset 24 hours earlier. He reported no past medical history and no cardiovascular risk factors apart from e-cigarette smoking. He received the second dose of COVID-19 mRNA BNT162b2 vaccine 60 hours before the onset of chest pain exacerbated by deep breathing and being in a supine position. The chest pain was exacerbated by deep breathing and the supine position. It radiated to the back and the left arm and was responsive to non-steroidal anti-inflammatory drugs. (…) Anti-inflammatory therapy was prescribed, resulting in pain relief. Serological tests for the detection of antibodies against the common causes of myocarditis were all negative. During hospitalization, the ECG showed a slow evolution of repolarization abnormalities, with T-wave inversion in inferior leads and normalization of ST-segment in the anterior and inferior leads (Figure 1B). No Q-wave developed. Continuous ECG monitoring showed only isolated premature ventricular contractions. The patient was discharged after one week in good condition, with troponin and inflammatory markers within normal ranges.

Discussion

Our case describes an episode of acute myocarditis after SARS-CoV-2 vaccination. Notably, it was a “usual” case of myocarditis, with an ACS-like presentation and a favorable course in terms of left ventricle function and arrhythmias. The causal relation between vaccination and myocarditis is strongly supported by their strict temporal relationship.

In general, immunization-related myocarditis is rare and mainly occurs after vaccination against smallpox. Usually, it occurs 10 days after vaccination without life threatening complications. The exact immunological mechanisms linking vaccination and myocarditis are unknown. Experimental evidence suggests that a type III hypersensitivity mediated by immunocomplexes could play a role. Moreover, the activation of the antigen-presenting cells is crucial in preclinical models of myocarditis. In humans, pro-inflammatory triggers such as vaccination or infections can overwhelm the self-tolerance mechanism inducing heart-specific autoimmunity.

CASE REPORT: ACUTE FULMINANT MYOCARDITIS AND CARDIOGENIC SHOCK AFTER MESSENGER RNA CORONAVIRUS DISEASE 2019 VACCINATION REQUIRING EXTRACORPOREAL CARDIOPULMONARY RESUSCITATION

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8586196/

Abstract

Recently, myocarditis following messenger RNA (mRNA) coronavirus disease 2019 (COVID-19) vaccination has become an important social issue worldwide. According to the reports so far, myocarditis related to mRNA COVID-19 vaccination is rare and usually associated with a benign clinical course without intensive care or any sequelae of fulminant myocarditis. Here, we report a case of acute fulminant myocarditis and cardiogenic shock after the mRNA COVID-19 vaccination, requiring extracorporeal cardiopulmonary resuscitation. Clinicians should keep in mind the possibility of progression to fulminant myocarditis in patients who presented with suggestive symptoms or signs of myocarditis after the COVID-19 vaccination.

Discussion

The present case gives important clinical messages in the management of the COVID-19 vaccine related myocarditis. First, myocarditis or pericarditis may be a significant differential diagnosis of chest pain after the COVID-19 vaccination. Second, COVID-19 vaccination related myocarditis is not always associated with a mild form of myocarditis or benign clinical course. As demonstrated in the present case, the possibility of disastrous fulminant myocarditis should be carefully monitored. Third, the prompt initiation of a temporary mechanical circulatory support such as venoarterial extracorporeal membrane oxygenation (VA-ECMO) is essential in most critically ill patients with fulminant myocarditis after COVID-19 vaccination, if indicated. Therefore, patients with COVID-19 vaccination-related myocarditis, which is not in the mild form, should be transferred and treated in centers for managing advanced heart failure.

Recently, a CDC Advisory Committee on Immunization Practice suggested a possible association between myocarditis and mRNA COVID-19 vaccines (Pfizer–BioNTech and Moderna) (1). There have been substantial cases of myocarditis or pericarditis after mRNA COVID-19 vaccination reported in the Vaccine Adverse Event Reporting System (VERAS) of the United States. According to these reports, Bozkurt et al.and Diaz et al. confirmed that myocarditis or pericarditis cases have occurred mostly in male adolescents and young adults, and shortly after (2–3.5 median days) COVID-19 vaccination, and more often after getting the second dose than after the first dose of mRNA COVID-19 vaccination. Most cases showed benign clinical course and responded well to conservative treatment, and thus CDC continues to recommend mRNA COVID-19 vaccination for individuals 12 years of age and older, given the risk of COVID-19 illness and severe related complications. As mentioned above, post-COVID-19 myocarditis has been regarded as a relatively benign one. In many reports, the patients with myocarditis that occurred after vaccination using mRNA COVID-19 vaccines were treated conservatively with or without medication and responded well. In one report, only 10% of patients with post-COVID-19 vaccination myocarditis were treated in an intensive care unit, and all the patients recovered (8). Contrary to most previous reports, the present case demonstrated that the clinical course of the COVID-19 vaccination-related myocarditis is not always benign as reported by others, and, currently, only a few case reports of fulminant myocarditis related to mRNA COVID-19 vaccination are available. Without the aid of VA-ECMO, the clinical course of the present case would be fatal. VA-ECMO seems to be more effective to reduce the mortality rate of COVID-19 vaccination related fulminant myocarditis as compared to other cases of fulminant myocarditis.

Conclusion

We reported a case of acute fulminant myocarditis complicated by cardiogenic shock after mRNA COVID-19 vaccination, and the effectiveness of ECMO support was essential for life saving in this special situation. Physicians should be alert to the possibility that myocarditis can rapidly progress after COVID-19 vaccination, and the prompt application of mechanical circulatory support is mandatory if called for.

ASSESSMENT OF MYOCARDIAL 18F-FDG UPTAKE AT PET/CT IN ASYMPTOMATIC SARS-COV-2–VACCINATED AND NONVACCINATED PATIENTS

SOURCE: https://pubs.rsna.org/doi/epdf/10.1148/radiol.230743

Introduction

While vaccines to prevent SARS-CoV-2 infection have demonstrated effectiveness in reducing morbidity and mortality related to respiratory complications (1,2), infrequent but important side effects associated with vaccination have also been reported. One such rare side effect that the mRNA vaccines have been linked to is myocarditis (3–7). Cardiac MRI (4,7,8) and fluorine 18 (18F) fluorodeoxyglucose (FDG) PET/CT imaging (9–11) have been routinely used in the noninvasive diagnosis of myocardial inflammation of diverse origin, including viral myocarditis, cardiac sarcoidosis, and cancer therapy–related cardiac dysfunction. Good agreement has been reported between late gadolinium enhancement or T2 hyperintensity on cardiac MRI scans and 18F-FDG uptake on PET scans in patients suspected of having myocarditis (12). A recent cardiac MRI study used late gadolinium enhancement and T2 intensity and reported myocardial injury from the SARS-CoV-2 vaccine was similar to that from myocarditis due to COVID-19, while severity was less (13). Similarly, an 18F-FDG PET/MRI study showed myocardial inflammation after COVID-19 illness (14), but it is not known whether 18F-FDG uptake would occur in asymptomatic individuals after SARS-CoV-2 vaccination. The purpose of the current study was to semiquantitatively and quantitatively assess myocardial 18F-FDG uptake on PET/CT scans in asymptomatic patients vaccinated against SARS-CoV-2 and asymptomatic nonvaccinated patients who underwent imaging for indications unrelated to myocardial inflammation.

Discussion

The aim of this study was to investigate myocardial 18F-FDG uptake on PET/CT scans in asymptomatic patients vaccinated against SARS-CoV-2 compared with uptake in nonvaccinated patients. In this observational study of patients who underwent PET/CT during comprehensive medical check-ups or to evaluate malignancies, patients who had received a SARS-CoV-2 mRNA-based vaccine showed increased myocardial 18F-FDG uptake on scans compared with nonvaccinated patients (median visual score, 2 [IQR, 0–3] vs 1 [IQR, 0–2]; $P < .001$; median SUVmax, 4.75 g/mL [IQR, 3.0–8.5 g/mL] vs 3.3 g/mL [IQR, 2.5–6.2 g/mL]; $P < .001$). This increase in myocardial 18F-FDG uptake in vaccinated patients was also observed in subgroup analyses that excluded individuals with cancer or homogeneous myocardial uptake. When patients were divided into groups based on the interval between vaccination and imaging, myocardial 18F-FDG uptake was higher in all vaccinated groups (median SUVmax range, 4.6–5.1 g/mL [range of IQRs, 2.9–8.6 g/mL]) compared with the nonvaccinated group (median SUVmax, 3.1 g/mL [IQR, 2.5–6.2 g/mL]; $P < .001$ to $P = .001$) except for the vaccinated group including individuals imaged more than 180 days after their second vaccination (median SUVmax, 4.5 g/mL [IQR, 2.7–9.3 g/mL]; $P = .15$). No difference in myocardial or axillary 18F-FDG uptake was observed between patients who received the BNT162b2 mRNA vaccine and those who received the mRNA-1273 vaccine. In 16 patients with more than one PET/CT study available, myocardial and axillary 18F-FDG uptake were higher on PET/CT scans obtained after vaccination than those obtained before vaccination. (…)

In conclusion, in a set of patients who underwent PET/CT for indications other than myocardial inflammation, those who had received a SARS-CoV-2 vaccine showed increased myocardial fluorine 18 (18F) fluorodeoxyglucose (FDG) uptake on images up to 180 days after their second vaccination compared with patients imaged before SARS-CoV-2 vaccination was available. Vaccinated patients showed higher myocardial 18F-FDG uptake on PET/CT scans compared with nonvaccinated patients, regardless of sex, age, or type of mRNA vaccine received. A prospective study would be needed to validate the findings of this study, including comparisons with cardiac enzyme levels, cardiac function, and non-mRNA vaccination.

A CASE REPORT: MULTIFOCAL NECROTIZING ENCEPHALITIS AND MYOCARDITIS AFTER BNT162B2 MRNA VACCINATION AGAINST COVID-19

SOURCE: https://www.mdpi.com/2076-393X/10/10/1651

Abstract

The current report presents the case of a 76-year-old man with Parkinson's disease (PD) who died three weeks after receiving his third COVID-19 vaccination. The patient was first vaccinated in May 2021 with the ChAdOx1 nCov-19 vector vaccine, followed by two doses of the BNT162b2 mRNA vaccine in July and December 2021. The family of the deceased requested an autopsy due to ambiguous clinical signs before death. PD was confirmed by post-mortem examinations. Furthermore, signs of aspiration pneumonia and systemic arteriosclerosis were evident. However, histopathological analyses of the brain uncovered previously unsuspected findings, including acute vasculitis (predominantly lymphocytic) as well as multifocal necrotizing encephalitis of unknown etiology with pronounced inflammation including glial and lymphocytic reaction. In the heart, signs of chronic cardiomyopathy as well as mild acute lympho-histiocytic myocarditis and vasculitis were present. Although there was no history of COVID-19 for this patient, immunohistochemistry for SARS-CoV-2 antigens (spike and nucleocapsid proteins) was performed. Surprisingly, only spike protein but no nucleocapsid protein could be detected within the foci of inflammation in both the brain and the heart, particularly in the endothelial cells of small blood vessels. Since no nucleocapsid protein could be detected, the presence of spike protein must be ascribed to vaccination rather than to viral infection. The findings corroborate previous reports of encephalitis and myocarditis caused by gene-based COVID-19 vaccines.

Discussion

While it is widely held that spike protein expression, and the ensuing cell and tissue damage will be limited to the injection site, several studies have found the vaccine mRNA and/or the spike protein encoded by it at a considerable distance from the injection site for up to three months after the injection. Biodistribution studies in rats with the mRNA-COVID-19 vaccine BNT162b2 also showed that the vaccine does not stay at the injection site but is distributed to all tissues and organs, including the brain. After the worldwide roll-out of COVID-19 vaccinations in humans, spike protein has been detected in humans as well in several tissues distant from the injection site (deltoid muscle): for instance in heart muscle biopsies from myocarditis patients, within the skeletal muscle of a patient with myositis and within the skin, where it was associated with a sudden onset of Herpes zoster lesions after mRNA-COVID-19 vaccination.

The underlying diagnosis in this patient was Parkinson's disease, and one may ask what role, if any, this condition had played in the causation of the encephalitis, and the myocarditis detected at post-mortem examination. PD had been long-standing in the current case, whereas the encephalitis was acute. Conversely, there is no plausible mechanism and no case report of PD causing secondary necrotizing encephalitis. On the other hand, numerous cases have been reported of autoimmune encephalitis and encephalomyelitis after COVID-19 vaccination. Autoimmune diseases in organs other than the CNS have been reported as well (…). In the case reported here, it may be noted that the spike protein was primarily detected in the vascular endothelium and sparsely in the glial cells but not in the neurons. Nevertheless, neuronal cell death was widespread in the encephalitic foci, which suggests some contribution of immunological bystander activation, i.e., autoimmunity, to the observed cell and tissue damage. (…)

Conclusions

Numerous cases of encephalitis and encephalomyelitis have been reported in connection with the gene-based COVID-19 vaccines, with many being considered causally related to vaccination. However, this is the first report to demonstrate the presence of the spike protein within the encephalitic lesions and to attribute it to vaccination rather than infection. These findings corroborate a causative role of the gene-based COVID-19 vaccines, and this diagnostic approach is relevant to potentially vaccine-induced damage to other organs as well.

SEX-SPECIFIC DIFFERENCES IN MYOCARDIAL INJURY INCIDENCE AFTER COVID-19 MRNA-1273 BOOSTER VACCINATION

SOURCE: https://pubmed.ncbi.nlm.nih.gov/37470105/

Abstract

Aims: To explore the incidence and potential mechanisms of oligosymptomatic myocardial injury following COVID-19 mRNA booster vaccination.

Methods and results: Hospital employees scheduled to undergo mRNA-1273 booster vaccination were assessed for mRNA-1273 vaccination-associated myocardial injury, defined as acute dynamic increase in high-sensitivity cardiac troponin T (hs-cTnT) concentration above the sex-specific upper limit of normal on day 3 (48-96 h) after vaccination without evidence of an alternative cause. To explore possible mechanisms, antibodies against interleukin-1 receptor antagonist (IL-1RA), the SARS-CoV-2-nucleoprotein (NP) and -spike (S1) proteins and an array of 14 inflammatory cytokines were quantified. Among 777 participants (median age 37 years, 69.5% women), 40 participants (5.1%; 95% confidence interval [CI] 3.7-7.0%) had elevated hs-cTnT concentration on day 3 and mRNA-1273 vaccine-associated myocardial injury was adjudicated in 22 participants (2.8% [95% CI 1.7-4.3%]). Twenty cases occurred in women (3.7% [95% CI 2.3-5.7%]), two in men (0.8% [95% CI 0.1-3.0%]). Hs-cTnT elevations were mild and only temporary. No patient had electrocardiographic changes, and none developed major adverse cardiac events within 30 days (0% [95% CI 0-0.4%]). In the overall booster cohort, hs-cTnT concentrations (day 3; median 5, interquartile range [IQR] 4-6 ng/L) were significantly higher compared to matched controls (n = 777, median 3 [IQR 3-5] ng/L, $p < 0.001$). Cases had comparable systemic reactogenicity, concentrations of anti-IL-1RA, anti-NP, anti-S1, and markers quantifying systemic inflammation, but lower concentrations of interferon (IFN)-λ1 (IL-29) and granulocyte-macrophage colony-stimulating factor (GM-CSF) versus persons without vaccine-associated myocardial injury.

Conclusion: mRNA-1273 vaccine-associated myocardial injury was more common than previously thought, being mild and transient, and more frequent in women versus men. The possible protective role of IFN-λ1 (IL-29) and GM-CSF warrant further studies.

ABSTRACT 10712: OBSERVATIONAL FINDINGS OF PULS CARDIAC TEST FINDINGS FOR INFLAMMATORY MARKERS IN PATIENTS RECEIVING MRNA VACCINES

SOURCE: https://www.ahajournals.org/doi/10.1161/circ.144.suppl_1.10712

Abstract

This clinic has been using the PULS Cardiac Test (Predictive Health Diagnostics Co., Irvine, CA) a clinically utilized measurement of multiple protein biomarkers, which generates a score predicting the 5 yr risk (percentage chance) of a new Acute Coronary Syndrome (ACS) called the PULS Score. The score is based on changes from the norm of multiple protein inflammatory biomarkers including IL-16, a proinflammatory cytokine, soluble Fas, an inducer of apoptosis, and Hepatocyte Growth Factor (HGF) which serves as a marker for chemotaxis of T-cells into epithelium and cardiac tissue, among other markers. Elevation above the norm increases the PULS score, while decreases below the norm lowers the PULS score. The PULS score has been measured every 3-6 months in our patient population for 8 years. Recently, with the advent of the mRNA COVID 19 vaccines (vac) by Moderna and Pfizer, we tracked the changes of the PULS score and three of the inflammatory markers it measures in all of our patients consecutively receiving these vaccines.

This report summarizes those results. A total of 566 pts, aged 28 to 97, M:F ratio 1:1 seen in a preventive cardiology practice had a previously scheduled PULS test drawn from 2 to 10 weeks following the 2nd mRNA COVID shot and was compared to the pt's PULS test drawn 3 to 5 months previously pre-shot. Each vac pt's PULS score and inflammatory marker changes were compared to their pre-vac PULS score, thus serving as their own control. There was no comparison made with unvaccinated patients or pts treated with other vaccines.

Baseline IL-16 increased from 35+/-20 above the norm to 82 +/- 75 above the norm post-vac; sFas increased from 22+/- 15 above the norm to 46+/-24 above the norm post vac; HGF increased from 42+/-12 above the norm to 86+/-31 above the norm post vac. These changes resulted in an increase of the pre vac PULS score of predicted 11% 5 yr ACS risk to a post vac PULS score of a predicted 25% 5 yr ACS risk, based on data which has not been validated in this population. No statistical comparison was done in this observational study.

In conclusion, the mRNA vacs numerically increase (but not statistically tested) the markers IL-16, Fas, and HGF, all markers previously described by others for denoting inflammation on the endothelium and T cell infiltration of cardiac muscle, in a consecutive series of a single clinic patient population receiving mRNA vaccines without a control group.

INCREASED EMERGENCY CARDIOVASCULAR EVENTS AMONG UNDER-40 POPULATION IN ISRAEL DURING VACCINE ROLLOUT AND THIRD COVID-19 WAVE

SOURCE: https://www.nature.com/articles/s41598-022-10928-z

Discussion

The main finding of this study concerns with increases of 25% in both the number of CA calls and ACS calls of people in the 16–39 age group during the COVID-19 vaccination rollout in Israel (January–May, 2021), compared with the same period of time in prior years (2019 and 2020), as shown in Table 1. Moreover, there is a robust and statistically significant association between the weekly CA and ACS call counts, and the rates of 1st and 2nd vaccine doses administered to this age group. At the same time there is no observed statistically significant association between COVID-19 infection rates and the CA and ACS call counts. This result is aligned with previous findings which show increases in overall CA incidence were not always associated with higher COVID-19 infections rates at a population level 35,49,50, as well as the stability of hospitalization rates related to myocardial infarction throughout the initial COVID-19 wave compared to pre-pandemic baselines in Israel51. These results also are mirrored by a report of increased emergency department visits with cardiovascular complaints during the vaccination rollout in Germany52 as well as increased EMS calls for cardiac incidents in Scotland53.

MYOCARDITIS FOLLOWING MRNA VACCINATION AGAINST SARS-COV-2, A CASE SERIES

SOURCE: https://www.sciencedirect.com/science/article/pii/S2666602221000409

Abstract

Introduction
mRNA COVID-19 vaccines have emerged as a new form of vaccination that has proven to be highly safe and effective against COVID-19 vaccination. Rare adverse events including myocarditis have been reported in the literature.

Methods
Data were gathered from the electronic medical record of four patients personally treated by the authors.

Results
Four patients, ages 20 to 30, presented with myocarditis characterized by chest pain, elevations in troponin-I and C-reactive protein, and negative viral serologies two to four days following mRNA vaccine administration. One had a cardiac MRI showing delayed gadolinium enhancement in a subpericardial pattern. All experienced symptom resolution by the following day, and the two who have returned for follow-up had normal troponin-I and CRP values.

Discussion
Along with previously reported instances, these cases raise suspicion for a possible link between mRNA vaccines and myocarditis.

ASSOCIATION OF MYOCARDITIS WITH BNT162B2 MESSENGER RNA COVID-19 VACCINE IN A CASE SERIES OF CHILDREN

SOURCE: https://pubmed.ncbi.nlm.nih.gov/34374740/

Abstract

The BNT162b2 (Pfizer-BioNTech) messenger RNA COVID-19 vaccine was authorized on May 10, 2021, for emergency use in children aged 12 years and older. Initial reports showed that the vaccine was well tolerated without serious adverse events; however, cases of myocarditis have been reported since approval.

Objective

To review results of comprehensive cardiac imaging in children with myocarditis after COVID-19 vaccine.

Design, setting, and participants

This study was a case series of children younger than 19 years hospitalized with myocarditis within 30 days of BNT162b2 messenger RNA COVID-19 vaccine. The setting was a single-center pediatric referral facility, and admissions occurred between May 1 and July 15, 2021.

Main outcomes and measures

All patients underwent cardiac evaluation including an electrocardiogram, echocardiogram, and cardiac magnetic resonance imaging.

Results

Fifteen patients (14 male patients [93%]; median age, 15 years [range, 12-18 years]) were hospitalized for management of myocarditis after receiving the BNT162b2 (Pfizer) vaccine. Symptoms started 1 to 6 days after receipt of the vaccine and included chest pain in 15 patients (100%), fever in 10 patients (67%), myalgia in 8 patients (53%), and headache in 6 patients (40%). Troponin levels were elevated in all patients at admission (median, 0.25 ng/mL [range, 0.08-3.15 ng/mL]) and peaked 0.1 to 2.3 days after admission. By echocardiographic examination, decreased left ventricular (LV) ejection fraction (EF) was present in 3 patients (20%), and abnormal global longitudinal or circumferential strain was present in 5 patients (33%). No patient had a pericardial effusion. Cardiac magnetic resonance imaging findings were consistent with myocarditis in 13 patients (87%) including late gadolinium enhancement in 12 patients (80%), regional hyperintensity on T2-weighted imaging in 2 patients (13%), elevated extracellular volume fraction in 3 patients (20%), and elevated LV global native T1 in 2 patients (20%). No patient required intensive care unit admission, and median hospital length of stay was 2 days (range 1-5). At follow-up 1 to 13 days after hospital discharge, 11 patients (73%) had resolution of symptoms. One patient (7%) had persistent borderline low LV systolic function on echocardiogram (EF 54%). Troponin levels remained mildly elevated in 3 patients (20%). One patient (7%) had nonsustained ventricular tachycardia on ambulatory monitor.

Conclusions and relevance

In this small case series study, myocarditis was diagnosed in children after COVID-19 vaccination, most commonly in boys after the second dose. In this case series, in short-term follow-up, patients were mildly affected. The long-term risks associated with postvaccination myocarditis remain unknown. Larger studies with longer follow-up are needed to inform recommendations for COVID-19 vaccination in this population.

MYOCARDITIS AND PERICARDITIS AFTER VACCINATION FOR COVID-19

SOURCE: https://jamanetwork.com/journals/jama/fullarticle/2782900

Discussion

Two distinct self-limited syndromes, myocarditis and pericarditis, were observed after COVID-19 vaccination. Myocarditis developed rapidly in younger patients, mostly after the second vaccination. Pericarditis affected older patients later, after either the first or second dose.

Some vaccines are associated with myocarditis, including mRNA vaccines, and the Centers for Disease Control and Prevention recently reported a possible association between COVID-19 mRNA vaccines and myocarditis, primarily in younger male individuals within a few days after the second vaccination, at an incidence of about 4.8 cases per 1 million. This study shows a similar pattern, although at higher incidence, suggesting vaccine adverse event underreporting. Additionally, pericarditis may be more common than myocarditis among older patients.

Study limitations include cases missed in outside care settings and missed diagnoses of myocarditis or pericarditis (which would underestimate the incidence), as well as inaccurate EMR vaccination information. Temporal association does not prove causation, although the short span between vaccination and myocarditis onset and the elevated incidence of myocarditis and pericarditis in the study hospitals lend support to a possible relationship.

COVID-19 VACCINATION-ASSOCIATED MYOCARDITIS IN ADOLESCENTS

SOURCE: https://pubmed.ncbi.nlm.nih.gov/34389692/

Abstract

Objectives
In this study, we aimed to characterize the clinical presentation, short-term prognosis, and myocardial tissue changes as noted on cardiovascular magnetic resonance (CMR) or cardiac MRI in pediatric patients with coronavirus disease 2019 vaccination-associated myocarditis (C-VAM).

Methods
In this retrospective multicenter study across 16 US hospitals, patients <21 years of age with a diagnosis of C-VAM were included and compared with a cohort with multisystem inflammatory syndrome in children. Younger children with C-VAM were compared with older adolescents.

Results
Sixty-three patients with a mean age of 15.6 years were included; 92% were male. All had received a messenger RNA vaccine and, except for one, presented after the second dose. Four patients had significant dysrhythmia; 14% had mild left ventricular dysfunction on echocardiography, which resolved on discharge; 88% met the diagnostic CMR Lake Louise criteria for myocarditis. Myocardial injury as evidenced by late gadolinium enhancement on CMR was more prevalent in comparison with multisystem inflammatory syndrome in children. None of the patients required inotropic, mechanical, or circulatory support. There were no deaths. Follow-up data obtained in 86% of patients at a mean of 35 days revealed resolution of symptoms, arrhythmias, and ventricular dysfunction.

A SERIES OF PATIENTS WITH MYOCARDITIS FOLLOWING SARS-COV-2 VACCINATION WITH MRNA-1279 AND BNT162B2

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8219373/

Abstract

Wide availability of the 3 vaccines approved by the U.S. Food and Drug Administration for emergency use against SARS-CoV-2 has led to reports of adverse reactions not seen during clinical trials: We now report a series of patients who developed CMR-proven myocarditis shortly after vaccination.

Six previously healthy men (17-37 years of age) with no infectious prodrome developed severe chest pain and elevated troponin I within 2 days-4 days of their second vaccination (Figure 1). Five patients had ST-segment elevation on presentation, with 4 demonstrating no coronary artery obstruction. All patients had negative nasopharyngeal SARS-CoV-2 PCR testing. CMR revealed patchy midmyocardial increased T2 signal with corresponding late gadolinium enhancement consistent with the acute inflammation of myocarditis (Figure 1). Five patients had abnormal left ventricular systolic function. None of the patients developed any other complications, and all were discharged home.

Large clinical trials of both BNT162b2 and mRNA-1273 in more than 70,000 individuals in the United States showed good safety profiles for both of the mRNA-based vaccines and no reports of myocarditis (1,2). However, myocarditis has been described after other vaccinations, such as seasonal influenza (3) and smallpox (4) and regulatory agencies are evaluating the risk of COVID-19 vaccine-associated myocarditis based on post-Emergency Use Authorization reports. CMR findings in patients with suspected COVID-19 vaccine-associated myocarditis have not been well described in published reports, and our report tries to document some of these changes. Although the clinical presentation, CMR findings, and temporal association strongly suggest the possibility of vaccine-associated myocarditis in our 6 patients, we cannot conclude definitively that COVID-19 vaccine was causative or that other etiologies for myocarditis can be definitively excluded in our patients. Nevertheless, clinicians should be suspicious of myocarditis in recently vaccinated patients with symptoms consistent with this diagnosis.

LYMPHOHISTOCYTIC MYOCARDITIS AFTER AD26.COV2.S VIRAL VECTOR COVID-19 VACCINATION

SOURCE: https://www.sciencedirect.com/science/article/pii/S2352906721001573

Abstract
Coronavirus disease (COVID-19) has caused approximately 4.38 million deaths worldwide with 208 million individuals infected. In addition, many with COVID-19 disease or post-COVID-19 infection have experienced cardiac involvement, such as myocarditis, or cardiac arrhythmias. Fortunately, development of modified RNA (mRNA) and viral vector vaccines have curbed the incidence and mortality from COVID-19. Although countries, have demonstrated a decreased incidence of infection resulting from increased rates of COVID-19 vaccination, many individuals remain unvaccinated due to concerns of potential side-effects or complications. This journal published a case report on April 2021 suggesting a possible association between the Pfizer (mRNA) vaccine and myocarditis. Further reports have supported the association between the mRNA vaccine and the development of myocarditis in young adults and an older adult with previous history of COVID-19. It is important to make the distinction that this patient obtained a viral vector vaccine and no similar case of myocarditis has been reported.

Conclusion
Although a definite conclusion cannot be made on the cause of this patients' lymphohistiocytic myocarditis, a potential relationship between the viral vector COVID-19 vaccine can be suggested. Recent reports suggest a potential relationship between the mRNA vaccine and myocarditis in adults. In addition, this journal in April presented a case of myocarditis in a patient with a previous history of SARS-CoV-2 infection after his second mRNA COVID-19 vaccine has been reported. It is important to make the distinction that this patient obtained a viral vector vaccine. Eosinophilic myocarditis has been shown to present with acute biventricular heart failure, cardiogenic shock, myocardial infarction like syndrome and thrombosis, with or without peripheral eosinophilia. Similarly, this patient presented with signs and symptoms of acute myocardial infarction with elevated troponin, NT-ProBNP, electrocardiogram T wave abnormalities with emergent coronary angiography not revealing any significant obstructive disease. Although the myocardial infiltrate in this case was predominately lymphohistiocytic, eosinophils were also present.

This case suggests a potential relationship between the viral vector COVID-19 vaccine and the patient's lymphohistiocytic myocarditis resulting in severe biventricular cardiomyopathy and death. Although there have been no previous reports of cardiac involvement with the viral vector vaccine, the timing of the event and the lack of other identifiable etiologies suggest a relationship. Acute myocarditis may also be due to immune checkpoint inhibitors. This patient was previously treated with Pembrolizumab for malignant melanoma, but the last administration was over one year ago making this medication the unlikely cause. Although acute viral illness has also been well documented as a cause of myocarditis,, the lack of signs, symptoms, and negative viral panel polymerase chain reaction make this etiology unlikely. Treatment guidelines recommend high dose steroids and possible benefit from administration of IVIG. Although this patient received high doses of IV steroids, IVIG was not able to be administered due to rapid deterioration and patient death. Another important intervention which may improve patient outcome is mechanical support with VA-ECMO. In conclusion, this study suggests a potential relationship between the COVID-19 viral vector vaccine and lymphohistiocytic myocarditis. Although limited reports are currently available, increased vaccination will provide physicians data to further explore a possible relationship between cardiac involvement and the COVID-19 viral vector vaccine.

ASSOCIATION OF MYOCARDITIS WITH BNT162B2 MESSENGER RNA COVID-19 VACCINE IN A CASE SERIES OF CHILDREN

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8356143/

Findings

In this case series of 15 children who were hospitalized with myocarditis after receipt of the BNT162b2 messenger RNA COVID-19 vaccine for 1 to 5 days, boys were most often affected after the second vaccine dose, 3 patients had ventricular systolic dysfunction, and 12 patients had late gadolinium enhancement on cardiac magnetic resonance imaging. There was no mortality, and all but 1 patient had normal echocardiogram results on follow-up 1 to 13 days after discharge.

Meaning

COVID-19 vaccine-associated myocarditis may have a benign short-term course in children; however, the long-term risks remain unknown.

Design, Setting, and Participants

This study was a case series of children younger than 19 years hospitalized with myocarditis within 30 days of BNT162b2 messenger RNA COVID-19 vaccine. The setting was a single-center pediatric referral facility, and admissions occurred between May 1 and July 15, 2021.

Conclusions and Relevance

In this small case series study, myocarditis was diagnosed in children after COVID-19 vaccination, most commonly in boys after the second dose. In this case series, in short-term follow-up, patients were mildly affected. The long-term risks associated with postvaccination myocarditis remain unknown. Larger studies with longer follow-up are needed to inform recommendations for COVID-19 vaccination in this population.

MYOCARDITIS AFTER BNT162B2 VACCINATION IN A HEALTHY MALE

SOURCE: https://www.sciencedirect.com/science/article/pii/S0735675721005362

Abstract

Myocarditis following mRNA COVID-19 vaccination has recently been reported to health authorities in the United States and other countries. Cases predominately occur in young adult males within four days following the second dose of either the Moderna (mRNA-1273) or Pfizer-BioNTech (BNT162b2) vaccines. Although the number of cases reported have been small in comparison with the large number of people vaccinated, myocarditis may be a rare adverse reaction to the COVID-19 vaccination that is now only becoming apparent due to the widespread use of the vaccine. In this article, we present a case of a 20-year-old male with no prior medical history who presented to the emergency department (ED) with chest pain. He had received the BNT162b2 vaccine two days prior to his presentation to the ED. The patient had an elevated troponin at 89 ng/L which increased on repeat examination. His electrocardiogram showed diffuse concave ST segment elevations and a later MRI confirmed the diagnosis of myocarditis. Based on these findings, the patient was diagnosed with myocarditis. The patient had a previous infection with SARS-CoV-2 approximately two months prior to the onset of his symptoms, but since he had fully recovered before the time of his presentation to the ED, it is unlikely that the infection caused the myocarditis. To our knowledge, this is the first published case of myocarditis following BNT162b3 vaccination.

Discussion

There have been several cases of myocarditis following mRNA COVID-19 vaccination reported to authorities in the United States and Israel [6,7]. The U.S. Department of Defense (DoD) reported 14 military personnel were diagnosed with myocarditis following vaccination with either Moderna (mRNA-1273) or Pfizer-BioNTech COVID-19 vaccines. The majority of cases received the mRNA-1273 vaccine, and most instances of myocarditis appeared following the second vaccination. With 2.7 million military personnel vaccinated, the rate of myocarditis in this population was 0.52 per 100,000 individuals. The Israeli Ministry of Health reported 62 cases of myocarditis following mRNA COVID-19 vaccination. Most cases occurred after the second dose and the prevalence of myocarditis was higher in men under 30 years old (1 per 20,000 in males aged 16–30 vs. 1 per 100,000 in the general population).

The Advisory Committee on Immunization Practices (ACIP) COVID-19 Vaccine Safety Technical (VaST) session on May 17, 2021 reviewed presentations on myocarditis following mRNA vaccines from representatives of the DoD, the Vaccine Adverse Event Reporting System (VAERS), the Vaccine Safety Datalink, and the Veteran's Administration. They concluded cases predominately occurred in adolescents and young adult males following the second dose and within four days after vaccination. Although the Centers for Disease Control and Prevention claims reports of myocarditis cases following COVID-19 vaccination are within the expected baseline number, the members of VaST recommended that information should be provided to clinicians about the potential relationship between myocarditis and COVID-19 vaccination.

Despite news reports as well as a few cases reported to VAERS, only one case report of myocarditis following COVID-19 vaccination has been published to date. That report detailed a case of myocarditis that developed four days after receiving a second dose of the mRNA-1273 vaccine in a 24-year-old male with no prior history of cardiovascular disease. While our case demonstrates a clear temporal association of vaccine-related myocarditis and other potential causes of myocarditis are unlikely, a true cause-and-effect relationship could not be established nor determined. We hope this case provides emergency medicine physicians additional information on evaluating potential post COVID-19 vaccination myocarditis.

CARDIOVASCULAR MAGNETIC RESONANCE FINDINGS IN YOUNG ADULT PATIENTS WITH ACUTE MYOCARDITIS FOLLOWING MRNA COVID-19 VACCINATION: A CASE SERIES

SOURCE: https://jcmr-online.biomedcentral.com/articles/10.1186/s12968-021-00795-4

Abstract

Background
Messenger RNA (mRNA) coronavirus disease of 2019 (COVID-19) vaccine are known to cause minor side effects at the injection site and mild global systemic symptoms in first 24–48 h. Recently published case series have reported a possible association between acute myocarditis and COVID-19 vaccination, predominantly in young males.

Methods
We report a case series of 5 young male patients with cardiovascular magnetic resonance (CMR)-confirmed acute myocarditis within 72 h after receiving a dose of an mRNA-based COVID-19 vaccine.

Results
Our case series suggests that myocarditis in this setting is characterized by myocardial edema and late gadolinium enhancement in the lateral wall of the left ventricular (LV) myocardium, reduced global LV longitudinal strain, and preserved LV ejection fraction. All patients in our series remained clinically stable during a relatively short inpatient hospital stay.

Conclusions
In conjunction with other recently published case series and national vaccine safety surveillance data, this case series suggests a possible association between acute myocarditis and COVID-19 vaccination in young males and highlights a potential pattern in accompanying CMR abnormalities.

OCCURRENCE OF ACUTE INFARCT-LIKE MYOCARDITIS FOLLOWING COVID-19 VACCINATION: JUST AN ACCIDENTAL CO-INCIDENCE OR RATHER VACCINATION-ASSOCIATED AUTOIMMUNE MYOCARDITIS?

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8325525/

Discussion

The special and novel aspect of our present report is based on accurate and comprehensive cardiac phenotyping using CMR imaging in three patients presenting with an infarct-like clinical pattern following COVID-19 vaccination. Multi-parametric CMR—using amongst others robust LGE-imaging and T2-weighted edema imaging—allows to depict even subtle myocardial damages and to further differentiate between an acute inflammatory process vs. rather chronic myocardial scars. Moreover, the pattern of myocardial damage visualized by CMR gives some clues regarding the underlying disease etiology as well as pathophysiology. In this context, all three patients clearly demonstrated one to two LV myocardial locations of acute myocardial inflammation suggesting the presence of acute myocarditis. The respective subepicardial and/or intramural pattern (referred as non-ischemic pattern) precluded an "ischemic" origin of MINOCA in these patients. Since "viral" myocarditis is characterized by multi-focal presence of a non-ischemic LGE pattern—predominantly in the free inferolateral LV wall as well as the septum—the diagnosis of myocarditis was made in our patients. However, as illustrated in Fig. 2 (bottom panel), severe "viral" myocarditis is frequently characterized by a patchy pattern of LGE that is not only present in one to two segments. In contrast, the areas of myocardial damage in our three patients were limited and very well demarcated. Hence, these slight differences may either reflect a different severity of myocardial inflammation and/or a different underlying pathomechanism in case of COVID-19 vaccination-associated autoimmune myocarditis compared to common viral myocarditis. Future studies should, therefore, carefully consider the cardiac phenotype of myocarditis in those patients.

Importantly, the issue of potential COVID-19 vaccination-associated autoimmune myocarditis gets even more important when we consider younger people since (a) vaccination-associated adverse events were observed more frequently in younger study participants (aged < 55 years) in the respective approval studies and (b) younger people have a higher risk for immunological adverse effects due to higher reactogenicity. Hence, a rapid increase in reports of post-vaccination myocarditis will—unfortunately—not be surprising based on the available data, if large vaccination campaigns will start for younger people. Therefore, regarding current discussions addressing the risk–benefit ratio of COVID-19 vaccination of children and teenagers, vaccination-associated adverse effects—including autoimmune myocarditis—need to be considered carefully, since young people are at a very low risk for severe COVID-19 infection even without vaccination.

Finally, the present report clearly indicates that we will need to consider COVID-19 vaccination-associated autoimmune myocarditis as another possible (non-ischemic) cause of MINOCA. Hence, clinicians will start to routinely ask for the timing of COVID-19 vaccination in patients presenting with a MINOCA.

We cannot definitely exclude the presence of "viral" myocarditis in our cases (making COVID-19 vaccination an innocent bystander), since we did not perform invasive endomyocardial biopsy (EMB). Although EMB still represents the gold standard for diagnosis of myocardial inflammation[12], it was not really indicated in our cases due to preserved systolic function and rather rapid improvement in clinical symptoms in each patient. The absence of preceding infectious symptoms (such as respiratory or gastrointestinal symptoms) in our patients does not exclude a "viral" cause per se but makes it rather unlikely. In case of disease progression, the collection of invasive EMB samples would be indispensable.

MYOPERICARDITIS AFTER THE PFIZER MESSENGER RIBONUCLEIC ACID CORONAVIRUS DISEASE VACCINE IN ADOLESCENTS

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8253718/

Abstract

Reports have emerged of myocarditis and pericarditis predominantly after the second dose of the coronavirus disease messenger ribonucleic acid vaccine. We describe 13 patients aged 12-17 years who presented with chest pain within 1 week after their second dose of the Pfizer vaccine and were found to have elevated serum troponin levels and evidence of myopericarditis.

Discussion

We report 13 adolescents with myopericarditis after the second dose of the Pfizer mRNA COVID-19 vaccine. This cluster of cases was identifiable as the age of eligibility for vaccination broadened with Emergency Use Authorization by the Food and Drug Administration. Our hospital is the only freestanding children's hospital in Washington and serves as a tertiary referral institution. To our knowledge, at least 3 other cases in this age group have been cared for at other hospitals in the state. Using these numbers and Washington Department of Health data on immunization, we estimate a possible incidence of 0.008% in adolescents aged 16-17 years and 0.01% in those aged 12-15 years following the second dose.

All patients had evidence of myocardial inflammation and edema on CMR, similar to findings in limited case series of adults with post–COVID-19 vaccine myocarditis. Although the symptoms resolved rapidly in all patients, their CMR findings indicate the potential for myocardial fibrosis and unknown long-term impact. Accordingly, we are following the American Heart Association/American College of Cardiology recommendations for exercise restrictions in acute myocarditis for up to 6 months and long-term cardiac surveillance. In addition, follow-up CMR is planned for all patients at 3 months, which may allow us to shorten the period of exercise restriction.

We speculate that a hyperimmune response to the second dose of the vaccine is plausible. Children have demonstrated a more robust immune response to severe acute respiratory syndrome coronavirus 2 infection than adults, as observed in multisystem inflammatory syndrome in children. For noninferior immunogenicity, it is possible the interval between doses 1 and 2 should be longer in children than in adults or that a reduction in the content of dose 2 may be appropriate in individuals aged <18 years.

It is noteworthy that 2 of our cases had a family history of myocarditis in first-degree relatives. There is evidence that genetics may play a role in the susceptibility of patients to myopericarditis. This predisposition may increase the likelihood of inflammation and cardiac effects after the vaccine.

The Pfizer Phase 2/3 clinical trial included only 754 participants in the 16 to 17-year-old age group and 2260 in the 12- to 15-year-old age group. Approximately 50% were males. As noted earlier, we have estimated the incidence of myopericarditis in the younger group as nearly 0.01% of those receiving the second dose of vaccine. Owing to reporting issues, delays, and early inability of practitioners to associate myopericarditis with vaccine, this is likely an underestimate. Moreover, our Washington Department of Health vaccine data for these age groups are not segregated by sex. This adverse event likely would not be detected in the small population of males who received the study vaccine and highlights the need for aggressive postauthorization surveillance.

Although a causal relationship between vaccination and the development of myopericarditis cannot be concluded from a case series, the clustering in time as well as the uncommon occurrence of myopericarditis and the rapid resolution of symptoms and findings likely make this a unique vaccine-related event. Identification of myopericarditis as an adverse event should have high priority during investigations before and after authorization of COVID-19 vaccines and be considered by policy makers in the risk/benefit ratio in adolescents and children.

POPULATION-BASED INCIDENCE OF MYOPERICARDITIS AFTER COVID-19 VACCINATION IN DANISH ADOLESCENTS

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8658061/

Abstract

In this prospective nationwide multicenter study from Denmark, myopericarditis after Pfizer-BioNTech mRNA COVID-19 vaccination was identified in 13 males and 2 females between May 15 and September 15, 2021, among 133,477 vaccinated males and 127,857 vaccinated females 12–17 years of age, equaling 97 males and 16 females per million. In conclusion, the incidence of myopericarditis after COVID-19 vaccination among males appears higher than reports from the United States.

Myopericarditis is a complication to mRNA COVID-19 vaccines, especially in male adolescents and young adults. According to the US Vaccine Adverse Event Reporting System (VAERS), the rate of myopericarditis has been reported to be 56–69 per million vaccinated males 12–17 years of age and 8–10 per million vaccinated females 12–17 years of age. However, as underreporting is a limitation of VAERS, the estimates are encumbered with uncertainty.

In Denmark, the Pfizer-BioNTech mRNA COVID-19 vaccination was recommended from May 15, 2021, in individuals 16–17 years of age and from July 15, 2021, in individuals 12–15 years of age. We aimed to estimate the incidence of myopericarditis in adolescents after mRNA COVID-19 vaccination among vaccinated individuals based on a nationwide prospective population-based cohort study with detailed clinical phenotyping.

Discussion

This study is based on a prospective detailed phenotyping of myopericarditis cases after Pfizer-BioNTech mRNA COVID vaccination in the very well registered population of Denmark. Among individuals 12–17 years of age, the study revealed an incidence of 97 males and 16 females per million. The incidence among males was higher than the reported rates until now from the US VAERS by Gargano et al finding 63 cases per million male adolescents 12–17 years of age. Although that report was based on 8.9 million vaccinated adolescents, underreporting is one of the main limitations of this passive surveillance system.

The incidences in our study are encumbered with uncertainty due to the small population of Denmark. Further, our incidences may be overestimated due to possible inclusion of cases unrelated to the vaccine, but occurring in vaccinated adolescents, since myopericarditis without a known etiology is quite common among male adolescents.5 Such overestimation is expected to be similar in the reported rates from the US VAERS. We estimated the background incidence of myocarditis to be 12 male and 2 female adolescents per million during a four-month period. Thus, the incidence of mRNA COVID-19 vaccine induced myopericarditis among adolescents is likely to be 10% lower than the reported incidences.

On the contrary, our incidences may also be underestimated. First, cases may have gone undiagnosed due to lack of clinical suspicion of this new association between vaccination and myopericarditis. Accordingly, 4 patients were initially discharged without evaluation for myocarditis despite chest pain and fever following COVID vaccination. Second, the inclusion period ended 4 weeks after the first vaccine. As myopericarditis appears to be more frequent after the second dose, cases could have been missed if the second dose was not administered timely. Finally, the incidences could be underestimated if patients were admitted to Departments of Adult Cardiology. (…)

In conclusion, this population-based prospective study suggests the incidence of myopericarditis in male adolescents to be higher than previous reported and that more severe phenotypes of myopericarditis may occur.

UNUSUAL PRESENTATION OF ACUTE PERIMYOCARDITIS FOLLOWING SARS-COV-2 MRNA-1237 MODERNA VACCINATION

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8381757/

Abstract

Since the start of the pandemic, to date, around 180 million cases have been diagnosed with COVID-19 worldwide with an estimated 3.9 million death toll. Mass vaccination has taken place to control spread of infection with the most commonly used vaccines being Pfizer-BioNTech and Moderna. However, the adverse events associated with vaccination have not been fully investigated. Of concern are some serious cardiovascular events such as myocarditis, pericarditis or perimyocarditis development post-vaccination. In this report, we present an unusual case of acute perimyocarditis and pericardial effusion 10 days following the second dose of Moderna COVID-19 vaccination in Qatar. At the time of presentation, the patient presented with non-specific symptoms of headache, diarrhea, vomiting, lethargy and dehydration. COVID-19 polymerase chain reaction (PCR) was negative. Once admitted to the emergency department, she started to deteriorate with very low blood pressure readings reaching 40/33 mmHg which was treated with aggressive fluid resuscitation. After 5.5 liters of intravenous fluids, echocardiography and electrocardiogram (ECG) were performed. Findings were consistent with pericardial effusion, signs of impending cardiac tamponade and acute perimyocarditis. Cardiac biomarkers including troponin T and pro-brain natriuretic peptide (BNP) were elevated. Hospital course was complicated with cardiac arrest, acute kidney injury, disseminated intravascular coagulation (DIC) and hemodynamic instability. Eventually, the patient recovered after a three-week hospital stay and was discharged on non-steroidal anti-inflammatory medication (NSAIDs). This case report highlights the hospital course and outcome linking the second dose of Moderna vaccination and the development of perimyocarditis.

Conclusions

Despite the rising need for the COVID-19 vaccines worldwide, further investigations are required taking into consideration the recent reported literature on possible side effects. Perimyocarditis, in particular, might be the current interest with very recent literature reported by the CDC.

It is also crucial that as physicians we keep an open mind when diagnosing patients. Our 29-year old patient presented with atypical symptoms pointing to an unlikely diagnosis of perimyocarditis. The presence of atypical or vague symptoms post-COVID-19 vaccination should raise the suspicion for possible adverse events. We recommend thorough investigations for patients presenting to the emergency, such as CBC, renal function test, liver function test, ECG, cardiac biomarkers and echocardiography, so as not to miss any important diagnoses. Lastly, we also recommend more research to be done on this topic, specifically to establish the incidence rate between the Moderna vaccination to perimyocarditis and the long-term effects associated with this link.

Vascular and Inflammatory Disorders

Vasculitis	Inflammation of blood vessels caused by the immune system attacking them. It can affect various organs and tissues, leading to symptoms like fever, fatigue, and organ damage.
Cutaneous Adverse Effects	Undesirable skin reactions resulting from various causes, such as medications, infections, or environmental factors. These effects manifest as changes in the skin's appearance, texture, or function. Examples include rashes, itching, redness, blistering, or peeling.
Lymphadenopathy	Abnormal enlargement of lymph nodes, which are small, bean-shaped structures that play a crucial role in the immune system. This condition often indicates an underlying infection, inflammation, or, in some cases, cancer. Symptoms may include swollen and tender lymph nodes.

PROPYLTHIOURACIL-INDUCED ANTINEUTROPHIL CYTOPLASMIC ANTIBODY-ASSOCIATED VASCULITIS AFTER COVID-19 VACCINATION

SOURCE: https://pubmed.ncbi.nlm.nih.gov/34451967/

Abstract

We report the case of a patient who developed antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis (AAV) after receiving the coronavirus disease 2019 (COVID-19) vaccine BNT162b (Pfizer-BioNTech). A 37-year-old Japanese woman had been taking propylthiouracil for Graves' disease. She had erythema on her forearm on the 12th day after receiving the first dose of the vaccine, fever on the 13th day, and redness and swelling of her left auricle on the 25th day. Her serum myeloperoxidase-ANCA and proteinase 3-ANCA levels, which were negative before the Graves' disease treatment, were elevated. She had unilateral auricular symptoms but no other typical relapsing polychondritis findings. She was diagnosed with propylthiouracil-induced AAV. She was treated with oral glucocorticoids, and her symptoms improved. Propylthiouracil is considered to be the main cause of the onset of AAV in this case, but it cannot be ruled out that BNT162b may have had some effect on the onset of the disease. Although the development of propylthiouracil-induced AAV in this case may have been incidental and unrelated to the vaccination, this report provides important data for evaluating the safety of the vaccine.

Discussion

The safety profile of BNT162b is characterized by injection site pain, fever, fatigue, and headache, with no reports of vasculitis. Since the vaccine was developed urgently, no long-term studies have been conducted. There are still concerns about unknown long-term adverse effects of the vaccine. Several cases of thrombocytopenia have been reported after the administration of mRNA vaccines. In a report from the U.S. of 20 patients who developed thrombocytopenia after vaccination, nine patients had received the Pfizer–BioNTech vaccine and 11 received the Moderna vaccine. All 20 patients were hospitalized and most of them presented with petechiae, bruising, or mucosal bleeding with the onset of symptoms between 1–23 days (median 5 days) after vaccination. The majority of patients' platelet counts at presentation were ≤10 × 109/L (range 1–36 × 109/L; median 2 × 109/L). Most of those patients were successfully treated with corticosteroids and intravenous immunoglobulin (IVIG), suggesting that their thrombocytopenia may have been due to secondary immune thrombocytopenia (ITP) after mRNA vaccination. Each year in the U.S., approx. 50,000 adults are diagnosed with ITP. Given the size of the vaccinated population, the incidence of ITP after vaccination is probably not higher than the incidence of cases that occur otherwise. It is unclear whether these cases are secondary ITP caused by vaccination. Although the cases are rather rare, the potential of the Pfizer–BioNTech and Moderna vaccines to ITP cannot be ruled out and requires continued surveillance.

NEPHROTIC SYNDROME AND VASCULITIS FOLLOWING SARS-COV-2 VACCINE: TRUE ASSOCIATION OR CIRCUMSTANTIAL?

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8344645/

Abstract

The immunologic response following several varieties of vaccination (especially meningococcal C conjugate vaccines) has been described as a potential trigger for the development of nephrotic syndrome (NS). Coronavirus disease 2019 (COVID-19) vaccine, administered worldwide, appears to be safe. However, rare reports of both *de novo* and recurrent NS and vasculitis are emerging.

Vaccines for the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) have been developed in an accelerated manner as a response to a pandemic. They use different mechanisms to generate immunity. Pfizer BNT162b2 and Moderna mRNA-1273 use a pioneer mechanism, a lipid nanoparticle nucleoside-modified mRNA that encodes SARS-CoV-2 spike (S) protein, which medicates host attachment and viral entry. AstraZeneca uses a replication-deficient chimpanzee adenovirus vector, containing the SARS-CoV-2 S protein. Studied subjects generated T cell response, CD8+ and CD4+ expansion, to a Th1-biased response with production of Interferon-γ, tumor necrosis factor-α (TNF-α), interleukin-2 and antibody (Ab) production predominantly of immunoglobulin G1 (IgG1) and IgG3 subclasses. These immune responses might be associated with a recurrence of glomerular disease or as a possible trigger for podocytopathies.

To date, 11 NS [new onset (5 patients) and relapsed (6 patients)] linked to minimal change disease (MCD) (10 patients) or membranous nephropathy (1 patient) after SARS-CoV-2 vaccines—Pfizer BNT162b2 (4 patients, 3 patients), Moderna mRNA-1273 (1 patient, 0 patient), AstraZeneca (0 patient, 2 patients) or SINOVAC (0 patient, 1 patient) vaccine have been reported (Table 1). All cases appeared 3 days to 2 weeks after the first vaccine dose followed by remission under corticosteroid treatment, except in one patient with underlying diabetic change nephropathy.

A CASE OF ANCA-ASSOCIATED VASCULITIS AFTER AZD1222 (OXFORD–ASTRAZENECA) SARS-COV-2 VACCINATION: CASUALTY OR CAUSALITY?

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8372491/

Findings

We report a case of a 63-year-old man with a nonrelevant medical background, previously normal kidney function, and no previous adverse reactions to vaccination. He was admitted to the hospital after noting 3 episodes of hemoptysis 7 days after his first dose of the AZD1222 vaccine. He had taken acetaminophen and acetylsalicylic acid for a flu-like syndrome, which appeared 48 hours after vaccination. Diagnostic workup showed creatinine 257.2 µmol/l with proteinuria ++ and mild hematuria. Chest X-ray showed infiltration in the left lower lung field. Diagnostic tests for SARS-CoV-2 were negative. Anti-myeloperoxidase antibodies (pANCA) were positive (12 UI/ml). Treatment for ANCA-associated vasculitis was initiated (high-dose i.v. glucocorticoids, followed by a tapering course of oral prednisone reduction [60 mg/d for 1 month followed by a decrease of 10 mg every 2 weeks], and oral cyclophosphamide). Plasma exchange was not instituted as the hemoptysis was self-limited without anemia or hemodynamic instability. Kidney biopsy showed focal extracapillary proliferation and crescent formation, resulting in a diagnosis of a focal class of ANCA-associated pauci-immune glomerulonephritis according to the Berden classification (Figure 1). Hemoptysis disappeared during admission, and progressive recovery of kidney function was observed. Creatinine improved initially with high-dose glucocorticoids to 247.5 µmol/l at 5 days after admission, creatinine was 252 µmol/l at discharge after 18 days of admission, and the last creatinine was 184.8 µmol/l after 6 weeks of treatment. Our patient had not developed an antibody response to the SARS-CoV-2 spike protein 2 months after the first AZD1222 vaccine.

To our knowledge, no cases of ANCA vasculitis have been reported after viral vector coronavirus disease 2019 vaccines, but they have been described after influenza vaccination.3 To our knowledge, this is the first case of ANCA vasculitis after the AZD1222 vaccine so far.4 In our patient, causality is based on temporal association, although we cannot demonstrate a direct link with vaccination.

IMAGES IN VASCULAR MEDICINE: LEUKOCYTOCLASTIC VASCULITIS AFTER COVID-19 VACCINE BOOSTER

SOURCE: https://journals.sagepub.com/doi/10.1177/1358863X211055507

Abstract

A 65-year-old man developed purpuric palpable lesions of the legs 2 days after receiving his third dose (booster) of Pfizer BioNTech vaccination against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Panels A and B). He received his initial vaccinations 4 months prior to receiving his booster injection. He denied any prior SARS-CoV-2 infection. He denied any systemic symptoms. The patient has a history of diabetes and hypertension for which he is on metformin and lisinopril, respectively; he otherwise has no other medical problems. Punch biopsy of the leg showed neutrophilic inflammation with fibrinoid necrosis and fragmented neutrophilic nuclei (leukocytoclasis), consistent with leukocytoclastic vasculitis (LCV). He was treated with one dose of triamcinolone 60 mg (IM), oral prednisone (tapered from 60 mg/d to 10 mg/d), along with topical clobetasol propionate and mupirocin.

Discussion

LCV is a cutaneous, small-vessel vasculitis characterized by deposition of immune complexes in the dermal capillaries and venules. Half of all cases of LCV are idiopathic; among secondary LCV, infections and medications are the most common triggers. Numerous medications have been implicated, including several antibiotics, furosemide, allopurinol, nonsteroidal antiinflammatory drugs (NSAIDs), amiodarone, metformin, warfarin, and several vaccines, including the influenza, hepatitis B (HBV), Bacille Calmette-Guérin (BCG), and human papillomavirus (HPV) vaccines. Most cases of cutaneous LCV are mild and resolve with supportive measures; if LCV is more chronic or resistant, oral corticosteroids can be used. For medication-induced LCV, withdrawal of the drug is crucial for resolution.

With the mass vaccination effort to address the coronavirus disease 2019 (COVID-19) pandemic caused by the SARS-CoV-2, there have been numerous reports of cutaneous manifestations after receiving the SARS-CoV-2 vaccine, including those manufactured by Moderna, Pfizer BioNTech, and Johnson & Johnson. The most commonly reported cutaneous manifestations are vaccine-related eruption of papules and plaques (V-REPP), bullous pemphigoid-like, dermal hypersensitivity reactions, herpes zoster, lichen planus-like, and pernio. There have been case reports of the development of LCV after the Moderna and Pfizer BioNTech SARS-CoV-2 vaccines; however, there have been no other reported cases of LCV development after the SARS-CoV-2 booster vaccine. The mechanism of SARS-CoV-2 vaccine-induced LCV is unclear but could potentially be driven by off-target immune activation after vaccination. There were no systemic manifestations in any of the reported cases and management in these cases varied from topical to oral steroids with resultant partial to complete resolution of the LCV.

REACTIVATION OF IGA VASCULITIS AFTER COVID-19 VACCINATION

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8260100/

Findings

Uncertainty persists as to the possibility that the COVID-19 vaccines might cause exacerbation of pre-existing autoimmune diseases.1 Here we report a case of reactivation of IgA vasculitis occurring after COVID-19 vaccination.

A woman aged 78 years with a history of IgA vasculitis with leukocytoclastic vasculitis, and renal and gastrointestinal involvement, had been in remission for 2 years with no immunosuppressant medication, before receiving the mRNA-1273 (Moderna) COVID-19 vaccine. At day seven post-vaccination, the patient had diarrhoea (6 times per day) and diffuse abdominal pain with acute onset (appendix p 1). Her vaccines were up to date, including yearly influenza, and previous vaccinations had never caused an IgA vasculitis reactivation. She had not taken any new medication and showed no signs of any infection including SARS-CoV-2 before vaccination with mRNA-1273, at admission to hospital, or during hospitalisation.

The patient's haemoglobin values decreased from 165 g/L to 143 g/L (normal range [N] 117–157 g/L) and laboratory tests including nasopharyngeal SARS-CoV-2 PCR test, large autoimmune panel, and infectious stool diarrhoea workup were in the normal range. However, the following tests were increased from pre-vaccine levels to 7 days post-vaccination: urea from 5·1 mmol/L to 10·2 mmol/L (N 2·9–6·4 mmol/L), creatinaemia from 96 µmol/L to 104 µmol/L (N 44–80 µmol/L), microhaematuria from 25 × 106/L to 150 × 106/L (N<26 × 106/L), C-reactive protein from 4 mg/L to 197 mg/L (N<10 mg/L), IgA from 2·25 g/L to 2·76 g/L (N 0·71–4·07 g/L), IgM from 0·19 g/L to 0·51 g/L (N 0·34–2·41 g/L), serum amyloid A from 10·2 mg/L to 2420 mg/L (N<6·4; appendix p 1). A CT scan showed sigmoid wall thickening with peripheral infiltration. The patient developed a palpable purpura in the hips and lower limbs. The patient was treated with methylprednisolone 1 mg/kg, and she improved rapidly with the disappearance of the purpura, gastrointestinal symptoms, and inflammatory syndrome, and improvement in renal function.

Investigations showed specific increases in the concentrations of anti-spike IgG, IgA, and IgM antibodies after mRNA-1273 vaccination, whereas concentrations of antibodies recognising the spike proteins of other human coronaviruses, such as anti-CoV HK41 IgG and IgA, did not increase (appendix p 1).

Moreover, an antinuclear antibody screening test on fixed HEp-2 cells showed the autoreactivity of the patient's IgA after mRNA-1273 vaccine administration, whereas serum taken from the patient before vaccination and serum from two healthy donors after mRNA-1273 vaccination did not show autoreactivity (appendix p 1). This immunofluorescence staining was observed specifically for IgA antibody binding to HEp-2 cells immediately after vaccination with binding reduced to background levels after 2 weeks of methylprednisolone treatment.

IgA vasculitis flares following vaccinations have been reported previously.2 Furthermore, it has been reported that patients with IgA nephropathy have a stronger IgA response to intramuscular influenza vaccine than do healthy controls.3 Moreover, two reports have described three cases of haematuria and IgA nephropathy flares following the second dose of mRNA COVID-19 vaccines in three individuals with biopsy-proven IgA nephropathy, two patients following the mRNA-1273 vaccine,4 and one after the BNT162b2 (BioNTech-Pfizer) vaccine.5

Taken together, these results might suggest a link between the increase in anti-SARS-CoV-2 spike IgA and the reactivation of pre-existing IgA vasculitis observed after vaccination; however a coincidence cannot be ruled out. It remains to be established whether activation of autoreactive B cells following vaccination results from the pre-existing or de novo mobilisation of autoreactive B cells producing IgA (or both).

LEUKOCYTOCLASTIC VASCULITIS AS A CUTANEOUS MANIFESTATION OF CHADOX1 NCOV-19 CORONA VIRUS VACCINE (RECOMBINANT)

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8646583/

Abstract

With the present COVID-19 vaccination drive across the world, adverse skin reactions post COVID-19 vaccine is expected. Majority of these reactions seen were transient or local injection site reactions. However, as the larger population is being vaccinated, certain uncommon dermatological presentations including leukocytoclastic vasculitis, pityriasis rosea, and exacerbation of pre-existing autoimmune diseases are now being reported. Among all the COVID-19 vaccines, most of these reactions are seen with messenger ribonucleic acid-based Pfizer/BioNTech (BNT162b2) and Moderna (mRNA-1273) vaccine. We report two cases of leukocytoclastic vasculitis following ChAdOx1 nCoV-19 corona virus vaccine (recombinant) that bring out potential new dermatological manifestations of recombinant corona virus vaccine being administered across the European, South American, and Asian countries. It is important for all health care workers and patients to be aware of the corona virus vaccine associated adverse cutaneous reactions.

Discussion

Leukocytoclastic vasculitis (LCV) as an adverse event to vaccination particularly to influenza vaccine has been reported. The mechanism of vasculitis is uncertain; however, it may be associated with hypersensitivity or abnormal immunological activation due to trigger of an underlying autoimmune or inflammatory disorder. Cutaneous vasculitis presenting with typical skin lesions were observed in mild as well as fulminant COVID-19 infection. Vasculitis in COVID-19 has been attributed to SARS-CoV-2 associated endotheliitis which could be either due to virus directly invading the endothelium or owing to inflammatory response that results in immune complex deposits in the vessels. SARS-CoV-2 antigens and vaccine proteins share structural similarities. Hence, with recombinant COVID-19 vaccine, inflammatory response to vaccine component encoding SARS-CoV-2 spike glycoprotein targeting endothelium resulting in endotheliitis and subsequent vasculitis could be hypothesized.

CUTANEOUS LYMPHOCYTIC VASCULITIS AFTER ADMINISTRATION OF COVID-19 MRNA VACCINE

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8420357/

Abstract

To date, several individuals have received COVID-19 vaccinations; therefore, the development of adverse skin reactions is expected. We report a peculiar cutaneous eruption post anti-Covid-19 vaccination (BNT162B2/Pfizer) in a woman without comorbidities, with a previous history of Covid 19 infection. A 51-year-old female patient, in good general health, had a symptomatic Covid-19 infection in April 2020 with fever, arthralgia, loss of taste and smell for 3 months and peripheral leg neuropathy that lasted for a few days; at this time, she did not present any skin manifestation. The initial anti-spike antibody value was 70.2 AU/ml (n.v. AU <12 ml).

In early January 2021, 6 h after the first dose anti-Covid-19 vaccination (BNT162B2/Pfizer), she presented edema and pain at the injection site and, the next day, arthralgia, fever, and the appearance of an itchy maculopapular rash. Initially, the eruption was localized on the upper limbs (volar surface) (Figure 1A), retro-auricular region and, 1-day later, on the trunk. Anti-spike antibody value at this time was >400 AU/ml and neutralizing antibodies titer was 1:640. Nasal swab proved negative for Sars-Cov-2 virus. Two skin biopsies for histological examination and direct immunofluorescence were done. By histology, a lymphocytic vasculitis with lymphocytes infiltrating the wall of small dermal vessels, with endothelial swelling was noticed (Figure 1B) in absence of thrombi. A predominance of T CD4+ lymphocytes (Dako) over T CD8+ cells (Dako) was noticed (Figure 1C,D); immunostaining with anti-SARS-CoV-2 nucleocapsid protein antibody (Sino Biological) did not show any specific reactivity. Direct immunofluorescence directed to IgG, IgM, IgA fibrinogen, and C3 (Dako, Denmark) did not reveal any deposits in the vessels. Further blood analyses to exclude concomitant viral reactivations (in particular HHV-6-DNA, HHV-7-DNA, EBV-DNA, and CMV-DNA) proved negative; parvovirus IgG and IgM were absent. Therapy with systemic antihistamine and local steroid led to the resolution of the manifestations within a week.

Due to the high level of immunization demonstrated by the serological test, the second dose of vaccine was not carried out. Vaccination in previously infected subjects is still debated as an opportunity to strengthen the defenses against the virus; however, the possible side effects are not yet fully known. New scientific evidences point to the possibility to perform a single dose vaccination in those who have a history of previous Covid-19 infection. In particular, a single dose of mRNA vaccine elicits very rapid immune responses in seropositive individuals with post-vaccine antibody titers comparable to or exceed titers found in naïve individuals who received two vaccinations. By now, the cutaneous patterns of symptomatic disease are well described, and the maculopapular manifestation is one of the most frequently seen and associated with a direct effect of the virus on the skin.

After the observation of our single case, it can be hypothesized that the immune response to the virus/vaccination is also involved in the development of skin eruptions, targeting small vessels. New insights about cross-reactivity between human tissue and SARS-CoV-2 have been recently demonstrated and the possibility of development of autoimmune disease reported. Immune response against the viral antigen following infection or vaccination can react with human tissue because of mimicry. The involvement of the vessel might explain the late vascular side effect such as chilblain eruption. In fact, histologically, the presence of lymphocytic vasculitis has been found also in Covid-19 chilblain eruption that; however, has in common with our case only the benign clinical course. Lymphocytic vasculitis can be find also in lupus erythematosus; however, direct immunofluorescence and autoimmune serology proved negative in our patient. The clinical features of our patient point to a post-vaccination rash similar to a paraviral eruption, rather than an allergic vaccine rash, which usually presents with anaphylactic or urticarial features. The timing of the eruption favors a post-vaccine eruption rather than a delayed reaction to SARS-CoV2 infection. In summary, we describe the occurrence of a peculiar post Covid-19 vaccination maculopapular rash characterized by lymphocytic vasculitis as the main histological finding, rapidly responding to systemic antihistamine and local steroid therapy.

SINOVAC COVID-19 VACCINE–INDUCED CUTANEOUS LEUKOCYTOCLASTIC VASCULITIS

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8501511/

Introduction

During the COVID-19 pandemic, several vaccine platforms have been generated against this virus, including inactivated whole-virus vaccines, namely CoronaVac (Sinovac Life Sciences). It is used particularly in Asia, the Middle East, and South America. Dermatologic reactions such as erythema, swelling, and urticaria have been reported. Cutaneous vascular inflammation, however, has not been reported from the use of Sinovac (CoronaVac). We, herein, report 2 cases of CoronaVac-induced cutaneous vasculitis.

Discussion

Vasculitis is a rare cutaneous adverse event after vaccination. It has been reported from inactivated vaccines such as influenza, hepatitis B, and hepatitis A vaccines. Among available COVID-19 vaccines, LCV was reported only after administering the messenger RNA (mRNA)–based platform (1 case from Pfizer-BioNTech [BNT162b2] and 2 cases from Moderna [mRNA-1273]). Interestingly, no cases were reported from the use of CoronaVac, which is based on inactivated whole virus.

Vasculitis can be triggered by infections, namely hepatitis B and C. It is worth noting that SARS-CoV-2 is notoriously responsible for skin findings associated with vascular pathology, such as chilblain-like lesions and retiform purpura. In addition, vasculitis has also been reported to be induced or exacerbated by SARS-CoV-2 infection. Although the pathogenesis of vaccine-related LCV remains obscure, it is speculated that immune complexes comprising inactivated viral specific antigens and the abnormal antibody deposition in the blood vessel walls may cause compliment activation, resulting in vascular damage. However, it is unknown as to whether the viral particles or the excipients of the vaccine are responsible as an antigen for such reactions.

Although the isolated cutaneous LCV is the most common form of vaccine-related vasculitides, it can also be an early sign of deleterious systemic conditions. Therefore, a prompt investigation for any systemic involvement in patients with vaccine-induced LCV should be undertaken. Our patients responded well to systemic corticosteroids and nonsteroidal antiinflammatory drugs. No recurrence was found in patient A after the second dose of CoronaVac. Similarly, recurrence of LCV after the second dose of COVID-19 mRNA vaccines did not occur. As most of the available COVID-19 vaccines are administered in 2 doses, more vasculitis cases need to be observed before an appropriate vaccination course can be recommended for those with LCV from the first injection.

In conclusion, to our knowledge, this is the first report of 2 CoronaVac-induced cases of cutaneous LCV. Health care professionals should be aware of the fact that the SARS-CoV-2 vaccine can trigger vascular inflammation.

COVID-19 VACCINATION INDUCED LYMPHADENOPATHY IN A SPECIALIZED BREAST IMAGING CLINIC IN ISRAEL: ANALYSIS OF 163 CASES

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8189756/

Discussion

In the current study we show an almost 4-fold increase in axillary lymphadenopathy detected on breast imaging in 2021 compared to 2019 and 2020 in the same medical center, an increase attributed to the massive COVID-19 vaccination campaign in Israel. Vaccination with the Pfizer-BioNTech vaccine was associated with a mostly radiologically detected, clinically subtle, ipsilateral lymphadenopathy in women who underwent breast imaging for a variety of clinical reasons: average and high risk women and in cancer free and breast cancer affected women.

Moderna reported on higher rates of axillary lymphadenopathy compared to prior vaccines; In the Moderna clinical trials, axillary swelling or tenderness was reported in 11.6% of patients (5.0% placebo) after the first dose and 16.0% (4.3% placebo) after the second, while per Pfizer trials, reports of ipsilateral axillary and supraclavicular lymphadenopathy in the first month after the second dose were imbalanced, with more cases in the vaccine group versus the placebo group, on clinical examination. In our study, most of the adenopathy 159/163 (97.5%) was subclinical and mostly detected by imaging only. Previously vaccine associated lymphadenopathy was anecdotally reported. Mehta et al described 3 cases of patients coming for routine screening mammography and ultrasound, and 1 patient presented due to palpable lump in the ipsilateral vaccinated arm. Eifer and Eshet reported a patient who underwent lumpectomy for breast cancer in whom contralateral lymphadenopathy and FDG uptake were attributed to reactive post vaccination lymphadenopathy. Özütemiz reported 5 cases of oncology patients with axillary lymphadenopathy that mimicked metastasis. (…)

Despite the limited number of cases where serology data were available, it seems that minimal cortical thickening is associated with negative serology for SARS-CoV-2 antibodies. It seems plausible that the absence of sizable adenopathy in individuals with a limited measurable antibody levels could be due to a low local immune response and could be related to the absence of vaccine induced antibody formation. This possibility needs to be tested in larger future studies.

The study limitations include a limited number of cases in a single medical center in Israel, and the selection bias that may have resulted. Furthermore since not all vaccinated women underwent axillary sonography, the precise rate of this subclinical phenomenon cannot be accurately determined. The strength of this study is the fact that it was done in a country, where approximately 90% of the adult population have been vaccinated (Israel Ministry of Health).

The clinical impaction of this study may be to defer breast imaging screening in asymptomatic individuals to 6 weeks after vaccination. In addition, it would be helpful to query all women undergoing breast imaging, if a vaccine were given, when and in which arm. In asymptomatic vaccinated women, subclinical lymphadenopathy as the only abnormal finding is in all likelihood secondary to vaccination, and radiological follow up is probably not indicated. Similarly, Keshavarz et al. have recently recommended in their review to rely on patient's clinical context and updated resources to prevent potential disease upstaging and change in therapy, regarding post vaccination axillary lymphadenopathy (21). Patients with current and past breast cancer should be vaccinated in the contralateral arm, as recommended by Becker et al (22). Patients with newly diagnosed breast cancer and ipsilateral lymphadenopathy should have a biopsy performed to exclude malignancy, even if they have a history of vaccination. BRCA carriers, although at a higher risk for breast cancer, should probably receive the same management as patients in average risk.

In conclusion, imaging detected axillary lymphadenopathy appears shortly after vaccination, with a mean cortical thickening of 5 mm, which starts to decrease after 4-5 weeks. In asymptomatic low risk women with normal breast exam, isolated axillary lymphadenopathy and a history of recent COVID-19 vaccination to the ipsilateral arm, a further investigation or follow up is most probably not warranted, though additional studies are required in order to confirm these preliminary observations.

COVID-19 POST-VACCINATION LYMPHADENOPATHY: REPORT OF CYTOLOGICAL FINDINGS FROM FINE NEEDLE ASPIRATION BIOPSY

SOURCE: https://onlinelibrary.wiley.com/doi/10.1002/dc.24863

Findings

Post-vaccination lymphadenopathy refers to reactive changes occurring within lymph nodes following vaccination, and it has been documented in multiple vaccine types. Recently, several case reports and series of COVID-19 post-vaccination lymphadenopathy, mostly focusing on the imaging aspects of the enlarged nodes, have been published. The finding of lymphadenopathy on sonography or magnetic resonance imaging, and/or increased fluorodeoxyglucose uptake in lymph nodes seen on positron emission tomography/computed tomography scans may prompt suspicion for a neoplastic process, especially if recent history of vaccination is not elicited. Awareness of this is particularly pertinent in female patients who may have post-vaccination axillary lymphadenopathy at the time of breast cancer screening. Some authors regard ipsilateral axillary lymphadenopathy within 4–6 weeks of any dose of COVID-19 vaccine to be most likely vaccination-related, with current proposed guidelines advocating cancer surveillance, screening or staging imaging to be performed either prior to vaccination or at least 4–6 weeks after the second dose. Additionally, the sonographic finding of a preserved fatty hilum favours a benign process.

In nanoparticle encapsulated mRNA vaccines, nanoparticle uptake and production of antigen occurs primarily at the site of injection and within the draining lymph node, followed by activation of antigen-presenting cells and priming of robust CD4+ T-cell responses, formation of germinal centres and production of antigen-specific antibodies. At the time of writing, the histological features of COVID-19 mRNA post-vaccination lymphadenopathy have only been described in two publications, in which three patients with either a personal or family history of breast cancer had biopsies of enlarged axillary lymph nodes showing follicular hyperplasia and interfollicular expansion of small lymphocytes, consistent with post-vaccination reactive lymphadenopathy.

To our knowledge, this is the first report of FNA cytology of COVID-19 post-vaccination lymphadenopathy in a patient without a prior history of malignancy, and the second documentation in the literature illustrating the cytomorphological features. Aalberg et al. have documented cytological findings in an axillary lymph node in a 73-year-old patient with renal cell carcinoma, showing a polymorphous lymphoid population with no evidence of metastatic disease. In the current tissue sample, we observed prominent germinal centre elements in the smears such as conspicuous tingible-body macrophages admixed with lymphohistiocytic aggregates and follicular dendritic cells, on a polymorphic lymphocytic background. Despite an increased proportion of larger lymphocytes, the overall mixed lymphoid population reflects a “milieu” typical of reactive lymph nodes, and suggests a pattern of reactive follicular hyperplasia that is congruent with the previously described histological findings. (…)

In the absence of accompanying worrisome clinical and radiological features, a mixed lymphoid population with increased numbers of activated lymphoid cells can still be in keeping with post-vaccination reactive lymphadenopathy and it may be appropriate to simply continue clinical or radiological follow-up. A carefully worded cytopathology report suggesting follow-up, and further investigations if lymphadenopathy persists (e.g., excision, core biopsy, flow cytometry), may be prudent.

As many countries ramp up COVID-19 vaccination coverage, we can only expect the clinical presentation of post-vaccination lymphadenopathy to increase in frequency. Thus, pathologists should be cognizant of the spectrum of cytological findings of COVID-19 post-vaccination lymphadenopathy, which may pose a potential diagnostic pitfall for false positive diagnosis of lymphoproliferative disease owing to the enriched population of larger activated lymphoid cells. Likewise, documentation of temporal relation to COVID-19 vaccination would also be helpful in clinical notes, when encountering lymphadenopathy in the usual locations for example, supraclavicular, cervical and axillary lymph nodes, as well as mention of the site of vaccination injection. Finally, further studies to document different cytological patterns of reactive lymphadenopathy may also be relevant, in view of the variety of vaccines that are available in the market.

EVOLUTION OF LYMPHADENOPATHY AT PET/MRI AFTER COVID-19 VACCINATION

SOURCE: https://pubs.rsna.org/doi/10.1148/radiol.2021210386

Introduction

A 56-year-old woman with no history of malignancy underwent research cardiac fluorine 18 fluorodeoxyglucose (FDG) PET/MRI the day after injection of the second dose of the Pfizer-BioNTech COVID-19 vaccine in her left deltoid muscle. PET/MRI showed unilateral left axillary lymphadenopathy with moderately increased FDG uptake (Figure). Follow-up PET/MRI was performed 5 weeks later according to the research protocol, which showed persistent left axillary lymphadenopathy but no FDG uptake.

Discussion

The first two COVID-19 vaccines authorized for emergency use by the U.S. Food and Drug Administration are highly immunogenic, with reports of ipsilateral axillary lymphadenopathy and FDG uptake after vaccination (1,2).

These images highlight that FDG uptake might resolve within a few weeks, whereas lymph node enlargement could persist beyond 5 weeks after injection (3). Lymph-adenopathy could be more pronounced and could last longer after the second vaccine dose (4).

Further evaluation of the prevalence and duration of vaccine-related lymph node changes at imaging is warranted to inform recommendations for the interpretation of ipsilateral axillary lymphadenopathy and FDG uptake. Knowledge of each patient's vaccination schedule may help guide the optimal timing of imaging for cancer screening.

MASSIVE CERVICAL LYMPHADENOPATHY POST-COVID-19 VACCINATION

SOURCE: https://pubmed.ncbi.nlm.nih.gov/34601889/

Abstract

The coronavirus disease 2019 (COVID-19) is a global pandemic caused by severe acute respiratory syndrome coronavirus 2. Rapid spread with rampant growth of cases and deaths brought forth an urgent need for novel therapies including vaccinations. The mRNA vaccines for COVID-19 disease have been implemented at an unprecedented scale in an effort to combat the unrelenting pandemic. Such a massive scale vaccination program is bound to coincide with adverse events related to treatment. We present a case of massive cervical lymphadenopathy in a 58-year-old male patient post-Moderna COVID-19 vaccination. Additional investigations did not identify malignancy and he was diagnosed with vaccine-related lymphadenopathy. Patient significantly improved with corticosteroid treatment within 2 days of admission. Lymphadenopathy is reported as the second most common local reaction to the Moderna vaccine. Promoting knowledge of this side effect, particularly in the setting widespread vaccination efforts, would allow for better management of cases, especially in relation to oncologic patients.

Discussion

In this case, exuberant lymphadenopathy was observed in the setting of COVID-19 vaccination. Initial differential diagnosis was concerning for infectious versus neoplastic etiology. However, further questioning revealed that this patient had received COVID-19 vaccination 2 days prior to onset of symptoms. For those who received the Moderna vaccine, reports of lymphadenopathy were more common (1.1%) when compared with the placebo group (0.6%), typically occurring within 2 to 4 days after vaccination. Given our patient's history and negative work up, it was concluded that lymphadenopathy has most likely developed because of recent COVID-19 vaccination.

Lymphadenopathy on the same side of vaccination has been previously reported as a side effect of other vaccinations. The median duration of lymphadenopathy across reported vaccinated COVID-19 cases was 1 to 2 days. Yet, many cases, including this one, report complete resolution of swelling weeks after treatment. The pathophysiology of vaccine-related lymphadenopathy remains unclear. One study proposes that vaccination performed too high on the arm, as opposed to injecting into the deltoid muscle, may be associated with such a response, though this hypothesis has not been validated. There are cases of transient fluorodeoxyglucose (FDG) uptake in the cervical lymph nodes of patients receiving positron emission tomography (PET) or CT scans after COVID-19 vaccination. Since interpretation of PET/CT scans of post-vaccination lymphadenopathy cases may be confounded with metastasis, delaying routine cancer surveillance imaging after vaccination in oncology patients may be beneficial to avoid confusion.

Though this was an unusual case of exuberant lymphadenopathy in the setting of COVID-19 vaccination, it is important for clinicians in internal medicine, infectious disease, emergency room, and otolaryngology to be familiar with this potential side effect that may involve cervical and axillary lymph nodes. Obtaining accurate vaccination history when encountering patients with new lymphadenopathy will aid in management and appropriate diagnostic tool utilization.

AUTOANTIBODY RELEASE IN CHILDREN AFTER CORONA VIRUS MRNA VACCINATION: A RISK FACTOR OF MULTISYSTEM INFLAMMATORY SYNDROME?

SOURCE: https://pubmed.ncbi.nlm.nih.gov/34835284/

Abstract

Multisystem inflammatory syndrome (MIS) is a new systemic inflammatory acute onset disease that mainly affects children (MIS-C) and, at a lesser frequency, adults (MIS-A); it typically occurs 3–6 weeks after acute SARS-CoV infection. It has been postulated and shown in adults that MIS may occur after SARS-CoV-2 vaccination (MIS-V). Our current case is one of the first published cases with a multisystem inflammatory syndrome in an 18-year-old adolescent after the SARS-CoV-2 vaccine from Pfizer/BionTech (BNT162b2), who fulfills the published level 1 criteria for a definitive disease: age < 21 years, fever > 3 consecutive days, pericardial effusion, elevated CRP/NT-BNP/Troponin T/D-dimeres, cardiac involvement, and positive SARS-CoV-2 antibodies. The disease starts 10 weeks after the second vaccination, with a fever (up to 40 °C) and was treated with amoxicillin for suspected pneumonia. The SARS CoV-2-PCR and several antigen tests were negative. With an ongoing fever, he was hospitalized 14 days later. A pericardial effusion (10 mm) was diagnosed by echocardiography. The C-reactive protein (174 mg/L), NT-BNP (280 pg/mL), and Troponin T (28 pg/mL) values were elevated. (…)

Discussion

To prove our hypothesis of BNT162b2 vaccination-induced autoantibody release in children, we measured the autoantibody against G-protein-coupled receptors in a girl with Hashimoto thyroiditis after vaccination (Case 2, Figure 2). We found a uniform increase of all these autoantibodies after the first vaccination, which returned to baseline six weeks after the second vaccination, but thyroid peroxidase autoantibodies further increased. She had no clinical side effects, but pacemaker monitoring showed an impairment of her arrhythmia, known of since early childhood and currently successfully treated with the dual chamber pacemaker. Moreover, while TPO antibodies significantly increased after vaccination, we had to increase her thyroxin treatment to normalize the elevated TSH values.

With these cases, we try to connect knowledge about the potential of SARS-CoV-2 to trigger autoimmunity with known cardiovascular complications of the disease and vaccination. Autoinflammation may explain the impact of SARS-CoV-2 infections on Hashimoto thyroiditis, as well as arrhythmogenesis and myocarditis.

At least, it seems not to be the whole virus but the spike protein that induces autoimmunity, the most imminent danger for children in this pandemic. (…)

The publication of the current cases is very important, in order to make doctors aware vaccination complications, such as MIS-C, if therapy with intravenous immunoglobulins can be initiated at an early stage. This awareness is essential when vaccinating children and adolescents who are not at increased risk of death from COVID-19. When informing the parents, we should refrain from claiming that the vaccination protects against MIS-C, as shown in the first case. (…)

We are aware that a misattribution of MIS-C as a severe complication of coronavirus vaccination can lead to increased vaccine hesitancy and blunt the global COVID-19 vaccination drive. However, the pediatric population is at a higher risk for MIS-C and a very low risk for COVID-19 mortality. At the currently high infection rate, the vaccination decision in childhood should be made dependent on the risk assessment of autoinflammatory diseases of COVID-19, compared with the vaccination. (…)

COAGULOPATHIES AFTER VACCINATION AGAINST SARS-COV-2 MAY BE DERIVED FROM A COMBINED EFFECT OF SARS-COV-2 SPIKE PROTEIN AND ADENOVIRUS VECTOR-TRIGGERED SIGNALING PATHWAYS

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8509779/

Abstract

Several SARS-CoV-2 vaccines based on mRNA, viral vectors, or inactivated SARS-CoV-2 virus have been approved and are being applied worldwide. However, the recent increased numbers of normally very rare types of thromboses associated with thrombocytopenia have been reported, particularly in the context of the adenoviral vector vaccine ChAdOx1 nCoV-19 from Astra Zeneca. The statistical prevalence of these side effects seems to correlate with this particular vaccine type, i.e., adenoviral vector-based vaccines, but the exact molecular mechanisms are still not clear. The present review summarizes current data and hypotheses for molecular and cellular mechanisms into one integrated hypothesis indicating that coagulopathies, including thromboses, thrombocytopenia, and other related side effects, are correlated to an interplay of the two components in the vaccine, i.e., the spike antigen and the adenoviral vector, with the innate and immune systems, which under certain circumstances can imitate the picture of a limited COVID-19 pathological picture.

Introduction

(...) However, recent reports of various types of venous thrombosis, particularly of normally very rare cerebral venous sinus thrombosis (CVST), in a timely correlation to vaccination against SARS-CoV-2 with ChAdOx1 nCoV-19 have raised safety concerns. A variety of vaccine-associated thrombotic events, including cerebral venous thrombosis, splanchnic vein thrombosis, pulmonary embolism, and other thromboses, as well as disseminated intravascular coagulation, has been reported in a time frame between a few days and three weeks after ChAdOx1 nCoV-19 vaccination against SARS-CoV-2 [6,7,8]. (…)

The underlying mechanism of action of these thrombotic events after adenoviral vector-based SARS-CoV-2 vaccines is still unknown. The present review summarizes the published data related to thrombotic events and different hypotheses for VITT-associated thrombotic events and presents an integrated model indicating that both SARS-CoV-2 spike protein and adenovirus vector can trigger signaling pathways that individually—and at a higher probability in combination—may trigger thromboses and thrombocytopenia following vaccination.

Discussion

(...) There is an additional mechanism that might accelerate the induction of anti-PF4 antibodies, which is the supposed superantigen feature of the spike protein.(…)

Although originally being locally applied, a limited local dissemination of adenoviral vaccines, e.g., via binding to endothelial cells together with the described NF-κB-triggered leaky expression of adenovirus genes in originally replication-incompetent adenoviral vectors may result in rare cases to self-amplifying cascades resulting in activated or damaged endothelial cells, activated and aggregated platelets, and activation of the coagulation system at sites distant to the application site, i.e., systemic prothrombotic procoagulation events together with a corresponding (consumption) thrombocytopenia as observed in rare cases of adenovirus vector-based SARS-CoV-2 vaccines.

Additional activation of the described molecular and cellular pathways may occur by impurities, such as the significant amounts of human heat shock proteins found in several ADT1222 vaccine preparations [105,128].

Together, these molecular and cellular mechanisms described in the previous sections may explain the higher prevalence of rare thromboses and thrombocytopenia following adenoviral vector-based anti-SARS-CoV-2 vaccines compared to mRNA-based anti-SARS-CoV-2 vaccines.

Neurological Disorders and Symptoms

Guillain-Barré Syndrome (GBS)	A rare neurological disorder where the body's immune system mistakenly attacks its peripheral nerves, leading to muscle weakness and, in severe cases, paralysis. It often starts with tingling or weakness in the legs and can progress to the upper body.
Myelitis, Acute Myelitis, Neuromyelitis	Myelitis is a general term describing inflammation of the spinal cord disrupting the normal functioning of nerve cells, with acute myelitis specifying a sudden onset of this inflammation. It can result in symptoms such as limb weakness, numbness, and difficulty with bowel and bladder control. Neuromyelitis encompasses disorders characterized by inflammation of both the spinal cord and optic nerves, with Neuromyelitis Optica being a prominent subtype featuring severe attacks impacting vision and spinal function.
Acute Hyperactive Encephalopathy	A sudden, severe alteration in brain function characterized by confusion, agitation, seizures, and sometimes coma. It can be caused by various factors, including infections, metabolic disturbances, or autoimmune reactions affecting the brain.
Immune-Mediated Disease Outbreaks	The body's immune system attacking its own tissues. Outbreaks refer to a sudden increase in the number of cases of a particular disease within a specific population. Immune-mediated disease outbreaks can be triggered by environmental factors, genetics, or infections.
Bell's Palsy	A sudden, temporary weakness or paralysis of the muscles on one side of the face. It is often linked to viral infections, particularly the herpes simplex virus, and is thought to result from inflammation of the facial nerve.

GUILLAIN-BARRÉ SYNDROME AFTER ASTRAZENECA COVID-19-VACCINATION: A CAUSAL OR CASUAL ASSOCIATION?

SOURCE: https://www.sciencedirect.com/science/article/pii/S0303846721004169

Abstract

We report a case of Guillain-Barré syndrome (GBS) following the first dose of Oxford/AstraZeneca COVID-19 vaccine with papilledema as atypical onset. As the COVID-19 vaccination campaign progresses worldwide, GBSs vaccine-related have been increasingly reported. After reviewing the available literature, considering the annual incidence of GBS, in this historical moment, the public health systems cannot afford an unjustified distrust in vaccines, caused by misinterpretation of epidemiological data. Nonetheless, it is important for clinicians to promptly recognize neurological complications potentially associated with COVID-19 vaccinations and report them to pharmacovigilance agencies.

Discussion

Considering the global COVID-19 vaccination campaign which is considered the largest in the history of humanity, neurologists should eagerly monitor and report GBS potentially related to it. To our best knowledge, few cases of GBS have been reported closely after the first dose of any COVID-19 vaccines. (…) Recently, two independently case series of GBS after first dose of ChAdOx1 have highlighted some recurrent characteristics, such as the severe bilateral facial paresis, as in the abovementioned case. Considering that COVID-19 vaccines induce immunization against SARS-CoV-2 spike proteins and SARS-CoV-2 spike protein can bind to sialic acid–containing glycoprotein and gangliosides on cell surfaces, an antibody cross-reaction may be the casual link between GBS and immunization to SARS-CoV-2. Since SARS-CoV-2 infection seems to be not related to a particular increase of GBS incidence, as happened in the case of Zika virus epidemic, we cannot conclude for a certain causal link between COVID-vaccine and GBS. Moreover, from a statistical point-of-view, considering an annual global incidence of 1–2 per 100,000 persons-years and an auspicious vaccination campaign of 5 billion persons, only by chance we could expect about 10,000–20,000 GBS in any 10-week period, including the four weeks between the two doses of vaccine. Thus is inevitable that many thousands of sporadic cases of GBS caused by other non-evident factors will appear temporally associated with COVID-19 vaccination.

In this historical moment, the public health systems cannot afford an unjustified distrust in vaccines, caused by misinterpretation of epidemiological data.Nonetheless, it is important for clinicians to promptly recognize neurological complications potentially associated with COVID-19 vaccinations and report them to pharmacovigilance agencies.

Indeed, the pharmacovigilance surveillance allowed to recognize the new disease-entity of thrombosis with thrombocytopenia syndrome (TTS), also known as vaccine-induced immune thrombotic thrombocytopenia (VITT), caused by ChAdOx1 nCov-19 vaccine.

Considering the absence at the beginning of clues of sensorimotor ascending symptoms and given the previous history of ChAdOx1 nCov-19 vaccination, a neurologist might have pointed as the cause of bilateral papilledema a condition of intracranial hypertension (IH) due to cerebral venous thrombosis in the context of TTS. Indeed, the present case had a troublesome onset that might have led to a misdiagnosis. Bilateral papilledema is a rare complication of GBS mainly described in younger women or children and even more rarely is reported as presenting symptom of GBS. (…)

One could speculate that viral-vectored vaccines may have triggered a systemic immunological reaction through molecular mimicry mechanisms, which may explain previously assumed association giving a specific “immunological signature” to GBS induced by COVID-19 vaccine. The few described cases are obviously not able to give us a statistical significance, so in the future it is urgent to pay attention to an underestimated parameter of CSF during the diagnostic workup of a GBS, namely the opening pressure, to confirm or refuse this association.

ASTRAZENECA COVID-19 VACCINE AND GUILLAIN- BARRÉ SYNDROME IN TASMANIA: A CAUSAL LINK?

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8447540/

Abstract

Covid-19 has been linked with the development of Guillain-Barre Syndrome (GBS), a rare immune-mediated demyelinating neuropathy. We report three cases of Guillain-Barre Syndrome and one case of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), presenting to a Tasmanian hospital, and review 15 other reported cases and discuss likely immunopathology. Nearly all reported cases of post-COVID-19 vacciation inflammatory demyelinating polyneuropathy are linked to AstraZeneca vaccination and a variant with bifacial weakness is the most reported form of GBS globally.

Discussion

Vaccines to prevent COVID-19 have been developed at a rapid pace (Mullard, 2020). More than 280 vaccines are in different phases of development including >100 in various stages of clinical trials (Mao et al., 2021). AZ vaccine consists of a chimpanzee adenovirus vector encoding the spike protein of SARS-CoV-2 (Madhi et al., 2021). Tens of millions of doses have been administered worldwide across more than 170 countries. The most likely mechanism of GBS induction is that antibodies to the S protein cross-react with gangliosides, forming autoantibodies leading to myelin damage.

Similar to earlier reports from Asia and Europe, our patients developed symptoms within three weeks after the first dose of AstraZeneca vaccine. One of our patients had bifacial weakness, which was also reported in twelve of the internationally reported cases. Two of our cases developed respiratory failure requiring ICU admission for ventilatory support, while one had an acute exacerbation of CIDP. Our diagnosis of GBS and CIDP was based on clinical features, CSF results and NCS results with Level 1 diagnostic certainty according to the Brighton criteria (van der Meché et al., 2001; Poser, 1981; Asbury and Cornblath, 1990).

In conclusion, an increasing number of case reports highlight the occurrence of inflammatory demyelinating polyneuropathy following administration of the AstraZeneca COVID-19 viral vector vaccine, emphasizing the need for vigilance regarding this specific adverse effect. Most reported cases involve a variant of GBS with bifacial weakness and respiratory failure. A potential link between GBS and AstraZeneca vaccine cannot be excluded at this time and indeed seems highly likely. Healthcare professionals are urged to report GBS post COVID-19 vaccination since accurate numbers will help us further confirm the potential causal link.

GUILLAIN-BARRÉ SYNDROME AFTER COVID-19 VACCINATION IN AN ADOLESCENT

SOURCE: https://www.pedneur.com/article/S0887-8994(21)00221-6/fulltext

Findings

Guillain-Barré syndrome (GBS) has been associated with SARS-CoV-2 infection in adults and children, and it has been noted as an adverse effect with the Janssen COVID-19 vaccine in adults. There have been no cases reported of children developing GBS after COVID-19 vaccination, to our knowledge.

We describe a child who developed GBS within one month of the administration of the second dose of the Pfizer-BioNTech COVID-19 vaccine. Our patient is a 14-year-old male who received the second dose of the Pfizer-BioNTech COVID-19 vaccine on June 11, 2021. He had previously never been diagnosed with COVID-19. On July 3, he experienced left lower extremity swelling up to the knee after a probable bee sting to the bottom of his left second toe, which resolved within two weeks without treatment. On July 11, he reported subjective facial weakness and subjective tongue swelling, for which he received oral prednisone at an urgent care facility. Owing to increasing facial weakness, he was evaluated in the emergency department on July 14, and he underwent diagnostic testing for common causes of facial palsy. No other weakness was reported on examination at that time. He was admitted on July 19 for progressive facial and limb weakness with areflexia. COVID-19 antigen testing was negative upon admission.

On examination, he had significant difficulty ambulating, bilateral facial weakness worse on the left, and 4+/5 strength throughout the left hemibody but preserved strength on the right side. Over the next few days, he became quadriparetic and was unable to ambulate independently. Breathing was never impaired.

This child's diagnosis of GBS was confirmed through clinical presentation; cerebrospinal fluid showing 4 white blood cells and 165 mg/dL protein, indicating cytoalbuminocytologic dissociation; and electrodiagnostic studies demonstrating a severe, generalized polyradiculoneuropathy, with demyelinating features indicating the acute inflammatory demyelinating polyradiculoneuropathy variant of GBS. Although this patient did not have any sensory losses, both acute inflammatory demyelinating polyradiculoneuropathy and the acute motor axonal neuropathy variants can cause pure motor symptoms.3 Additional cerebrospinal fluid and serum testing excluded alternative etiologies, including negative Lyme antibodies, Lyme polymerase chain reaction, and ganglioside antibodies.
Our patient was treated with 2 g/kg IVIg over 3 days. Beginning on the third day of his IVIg course, he demonstrated marked improvement in his facial and limb weakness. Before discharge, he was able to ambulate with assistance and went home with outpatient physical therapy seven days after admission. At his follow-up appointment in mid-August, he reported full resolution of his neurologic symptoms, and no neurologic abnormalities were noted on physical examination.

We are unaware of other pediatric cases of GBS reported in association with a COVID-19 vaccination. Although our patient experienced a probable bee sting in the time after his vaccination, we find it unlikely that this was a direct cause of our patient's GBS given the scarcity of case reports on this association4 and the quick resolution of localized symptoms. Following the 1976 National Influenza Immunization Program, which was associated with an increased risk of GBS up to 10 weeks after administration, there has been intense scrutiny of subsequent influenza vaccines. Results from analyses of subsequent vaccines have been uneven but are associated with at least a slight increased risk of GBS after many vaccinations in both children5 and adults,6 suggesting an etiological linkage. COVID-19 vaccines could trigger GBS via molecular mimicry or via a nonspecific immune response to the vaccine. The incidence of GBS in children is 0.34 to 1.34 cases per 100,000 person,7 so it is also possible that this case occurred coincidentally with the vaccine.

The onset of GBS within six weeks of vaccination suggests a possible causative association, but large-scale epidemiologic studies are required to determine if COVID-19 vaccination increases the risk of GBS in this population.

POST SARS-COV-2 VACCINATION GUILLAIN-BARRE SYNDROME IN 19 PATIENTS

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8478139/

Abstract

SARS-CoV-2 vaccinations are not free from side effects. Usually, they are mild or moderate but occasionally severe. One of these severe side effects is Guillain-Barré syndrome (GBS). This review summarizes and discusses GBS as a side effect of SARS-CoV-2 vaccinations (SCoVaG) based on recent research reports. Altogether, nine articles reporting 18 patients with SCoVaG were identified and one more report on another patient is under review. The age for the studies ranged between 20-86y. Nine patients were male, and ten were female. In all 19 patients, SCoVaG developed after the first dose of the vaccine. The Astra Zeneca vaccine was used in fourteen patients, the Pfizer vaccine in four patients, and the Johnson & Johnson vaccine was applied in one patient. The latency between vaccination and onset of GBS ranged from 3h to 39d. The treatment of SCoVaG included IVIGs (n=13), steroids (n=3), or no therapy (n=3). Six patients required mechanical ventilation. Only a single patient recovered completely and partial recovery was achieved in nine patients. In conclusion, GBS may develop time-linked to the first dose of a SARS-CoV-2 vaccination. Though a causal relationship between SARS-CoV-2 vaccinations and SCoVaG remains speculative, more evidence is in favour than against it.

Discussion

This narrative review shows that since the introduction of the SARS-CoV-2 vaccination in December 2020, at least 19 patients have been reported to experience SCoVaG time-linked to the first dose of a SARS-CoV-2 vaccination. Additionally, more than 300 SCoVaG patients were reported by the FDA and the EMA. In the majority of the 19 cases, SCoVaG developed after the application of a vector-based SARS-CoV-2 vaccine. The latency between vaccination and onset of SCoVaG was highly variable. The severity of the complications ranged from mild to severe and required mechanical ventilation in six patients. In most cases, the outcome was favourable, but only partial recovery was achieved based on the reporting date.

The presence of a causal relationship between vaccination and the occurrence of SCoVaG remains speculative, but several arguments can be raised in favour and against a causal relationship. Arguments favouring a causal relationship are that SARS-CoV-2 infections are associated with GBS development; GBS occurred time-linked to the vaccination; the vaccination stimulates the production of T-cells and antibodies, which could cross-react with the structures of the nerve roots; mRNA-based vaccines require modifications to ensure stability while avoiding pathogen-associated molecular patterns that may trigger an excessive inflammatory response; mRNA-based vaccines require utilizing lipid nanoparticle encapsulation to reach the intracellular machinery, which has been implicated in causing anaphylaxis; and SCoVaG responds to IVIGs and steroids. Arguments against a causal relationship are that the number of reported patients so far is low, that the latency was fairly long in one patient (39d), that the latency was extremely short in another patient (3h), that temporal association does not imply causality, and that GBS could have developed by chance as well. One would expect to see 900-2200 patients developing GBS within six weeks of receiving 1-dose vaccination (Johnson & Johnson) or 1500-3700 patients developing GBS within ten weeks of 2-dose vaccination (Pfizer and Moderna). It is to be noted that molecular mimicry requires a humoral response that requires 10-14d to develop. However, the immune-mediated inflammatory response is another postulated mechanism requiring less development time than molecular mimicry. (…)

In conclusion, this review illustrates that GBS may develop time-linked to the first dose of a SARS-CoV-2 vaccination. Whether there is a causal relationship between vaccination and GBS remains speculative. Still, more arguments in favour than against a causal relationship can be raised, suggesting that GBS can complicate SARS-CoV-2 vaccination in single cases. Despite adequate treatment, some patients may not recover completely. Those involved in the management of SARS-CoV-2 vaccination should remain vigilant for severe side effects in single patients. Early recognition and treatment of GBS may improve the outcome.

SENSORY GUILLAIN-BARRE SYNDROME FOLLOWING THE CHADOX1 NCOV-19 VACCINE: REPORT OF TWO CASES AND REVIEW OF LITERATURE

SOURCE: https://www.sciencedirect.com/science/article/pii/S0165572821002186

Abstract

Massive vaccination against COVID-19 has become a global priority. Simultaneously, concerns regarding the safety of vaccines are growing. We describe two patients who developed sensory Guillain-Barre syndrome (GBS) shortly after the first dose of the ChAdOx1 vaccine. We also summarize 12 published cases of GBS after ChAdOx1 vaccination, highlighting their unique clinical and paraclinical features. We propose a possible association between the risk of GBS and the ChAdOx1 vaccine and recommend surveillance for GBS following vaccination. Population-based studies are needed to determine causality and whether specific subpopulations are susceptible.

Discussion

A causal relationship between COVID-19 and GBS is under active discussion since the first report on their co-occurrence in January 2020 (Dalakas, 2020; Fantini et al., 2020; Keddie et al., 2021; Palaiodimou et al., 2021; Zhao et al., 2020). A large-scale population-based study reported that the incidence of the whole GBS did not increase during the pandemic (Keddie et al., 2021). However, a recent meta-analysis based on 11 cohorts found an increased risk of the demyelinating subtype in COVID-19 patients compared to non-infected or historical counterparts (Palaiodimou et al., 2021).

Conversely, little is known about the relationship between COVID-19 vaccines and GBS. No GBS occurred in clinical trials of COVID-19 vaccines, except for one among 19,630 Ad26.COV2·S recipients (Baden et al., 2021; Heath et al., 2021; Polack et al., 2020; Sadoff et al., 2021; Voysey et al., 2021). Although rare, we propose a possible association between GBS and the ChAdOx1 vaccine. The frequent observation of rare variants and demyelinating subtypes, which increased in COVID-19 GBS, further supports our suspicion. However, the pathophysiological mechanisms underlying this vaccine-associated neuro-autoimmunity remain elusive; whether antibodies against the spike protein could cross-react with peripheral nerve constituents is controversial (Dalakas, 2020, Fantini et al., 2020, Keddie et al., 2021). As for DNA vaccines (ChAdOx1 and Ad26.COV2·S), adenovirus vectors or aberrant splice variants may be alternative sources of autoimmunity (Almuqrin et al., 2021). Further mechanistic research is needed to demonstrate the pathophysiology of post-COVID-19 vaccine-GBS and whether a particular vaccine is associated with the increased risk.

Conclusion

We describe two cases of sensory GBS after ChAdOx1 vaccinations and provide a literature review on 12 additional GBS cases following the ChAdOx1 vaccine, highlighting their unique clinical and paraclinical features. Vigilance of GBS following COVID-19 vaccinations is mandatory to determine a causal association. Moreover, it would be interesting to investigate the overall outcomes of the post-COVID-19 vaccine-GBS and if there are populations at an increased risk.

Miller-Fisher Syndrome and Guillain-Barre Syndrome overlap syndrome in a patient post Oxford-AstraZeneca SARS-CoV-2 vaccination

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8634230/

Abstract

We describe a patient who developed bilateral oculomotor nerve palsy, ataxia, facial diplegia and lower limb weakness 2 weeks post-Oxford-AstraZeneca SARS-CoV2 vaccination, consistent with Miller-Fisher syndrome (MFS) and Guillain-Barre syndrome (GBS) overlap syndrome. Although some features of the patient's presentation were typical of recently reported cases of a rare GBS variant post-Oxford-AstraZeneca vaccination, including severe facial weakness and a lack of respiratory involvement, to our knowledge this is the first reported case of MFS associated with SARS-CoV2 vaccination. While postvaccination GBS remains rare, it appears to have a favourable prognosis, and recognising this entity is therefore important for patient counselling and monitoring for potential complications.

Discussion

To our knowledge, this case is the first to report the MFS-GBS overlap syndrome associated with the Oxford-AstraZeneca SARS-CoV2 vaccination. Recently, two case series have documented 12 patients who developed the rare BFP variant within 3 weeks following the first dose of the Oxford-AstraZeneca vaccination. Notably, patients in these series had a favourable prognosis, a lack of respiratory complications, and four had markedly elevated CSF protein (>1.9 g/L). Our case exhibited strikingly similar clinical characteristics, raising the possibility of a similar pathogenic mechanism, but also had classical features of MFS with ataxia, ophthalmoplegia and areflexia.

Several cases of MFS have also been documented following SARS-CoV-2 infection. Interestingly, although the GQ1b antibody is observed in 85% of MFS cases, all documented cases of MFS post SARS-CoV-2 infection have been anti-GQ1b negative, suggesting a novel immunopathogenic mechanism. The anti-GQ1b antibody was also negative in our case which may imply a shared mechanism to MFS post-SARS-CoV-2, perhaps via molecular mimicry of the SARS-CoV-2 spike protein.

We performed a literature review using PubMed, MEDLINE and Embase for all published postvaccination MFS cases up to 21 August 2021. The following keywords, ["Miller Fisher Syndrome"] AND ["vaccine" OR "post vaccination" OR "SARS-CoV-2" OR "COVID-19"], were used in the search strategy. There have been six prior case reports of postvaccination MFS: two following combined diphtheria, tetanus and pertussis vaccine (Tdap), one following seasonal influenza vaccine, one following combined Pneumovax and seasonal influenza vaccine, two following combined seasonal influenza and H1N1 vaccine, and one following H1N1 vaccine alone. All cases presented with symptoms from 5 days to 14 days postvaccination, except in one patient with HIV in which symptom onset was 40 days postseasonal influenza vaccine and 34 days post-H1N1 vaccine, respectively.

All previous cases of post-vaccination MFS had raised CSF protein of under 1 g/L. Our case is distinct in this respect, with a CSF protein of 2.99 g/L, but consistent with cases of the BFP variant post-Oxford-AstraZeneca Vaccine. Three previous cases had positive anti-GQ1b antibodies, and in two cases, GQ1b status was not reported. All cases were treated with intravenous immunoglobulin, except one case post-Tdap vaccine reported by Garg and Moudgil, which was treated with plasmapheresis. All cases of MFS following Tdap vaccine and one case postseasonal influenza vaccine had complete resolution of symptoms; however, the prognosis of other cases may have been confounded by the variable duration of follow-up.

Our case highlights the wide clinical spectrum of GBS variants and the need for close surveillance for atypical complications of the SARS-CoV2 vaccination. Although a coincidental relationship with the Oxford-AstraZeneca vaccination cannot be excluded, we feel that the temporal onset of clinical symptoms, the presence of anti-GQ1b seronegativity and the coexistence of the rare BFP variant that has emerged as an associated clinical syndrome makes this unlikely. The patient avoided respiratory and autonomic complications and is making a promising recovery, supporting the existing evidence for a good prognosis in post-SARS-CoV2 vaccine GBS.

ACUTE TRANSVERSE MYELITIS (ATM):CLINICAL REVIEW OF 43 PATIENTS WITH COVID-19-ASSOCIATED ATM AND 3 POST-VACCINATION ATM SERIOUS ADVERSE EVENTS WITH THE CHADOX1 NCOV-19 VACCINE (AZD1222)

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8107358/

Abstract

Although acute transverse myelitis (ATM) is a rare neurological condition (1.34-4.6 cases per million/year) COVID-19-associated ATM cases have occurred during the pandemic.

Case-finding methods

We report a patient from Panama with SARS-CoV-2 infection complicated by ATM and present a comprehensive clinical review of 43 patients with COVID-19-associated ATM from 21 countries published from March 2020 to January 2021. In addition, 3 cases of ATM were reported as serious adverse events during the clinical trials of the COVID-19 vaccine ChAdOx1 nCoV-19 (AZD1222).

Results

All patients had typical features of ATM with acute onset of paralysis, sensory level and sphincter deficits due to spinal cord lesions demonstrated by imaging. There were 23 males (53%) and 20 females (47%) ranging from ages 21- to 73- years-old (mean age, 49 years), with two peaks at 29 and 58 years, excluding 3 pediatric cases. The main clinical manifestations were quadriplegia (58%) and paraplegia (42%). MRI reports were available in 40 patients; localized ATM lesions affected ≤3 cord segments (12 cases, 30%) at cervical (5 cases) and thoracic cord levels (7 cases); 28 cases (70%) had longitudinally-extensive ATM (LEATM) involving ≥4 spinal cord segments (cervicothoracic in 18 cases and thoracolumbar-sacral in 10 patients). Acute disseminated encephalomyelitis (ADEM) occurred in 8 patients, mainly women (67%) ranging from 27- to 64-years-old. Three ATM patients also had blindness from myeloneuritis optica (MNO) and two more also had acute motor axonal neuropathy (AMAN).

Conclusions

We found ATM to be an unexpectedly frequent neurological complication of COVID-19. Most cases (68%) had a latency of 10 days to 6 weeks that may indicate post-infectious neurological complications mediated by the host's response to the virus. In 32% a brief latency (15 hours to 5 days) suggested a direct neurotropic effect of SARS-CoV-2. The occurrence of 3 reported ATM adverse effects among 11,636 participants in the AZD1222 vaccine trials is extremely high considering a worldwide incidence of 0.5/million COVID-19-associated ATM cases found in this report. The pathogenesis of ATM remains unknown, but it is conceivable that SARS-CoV-2 antigens –perhaps also present in the AZD1222 COVID-19 vaccine or its chimpanzee adenovirus adjuvant– may induce immune mechanisms leading to the myelitis.

SARS-COV-2 VACCINATION-INDUCED TRANSVERSE MYELITIS

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8384391/

Abstract

While mass immunization against coronavirus disease 2019 (COVID-19) rolls out around the globe, safety concerns and adverse events that need prompt evaluation are also emerging. We report a case of transverse myelitis and Bell's palsy after receiving Johnson and Johnson COVID-19 vaccination under the emergency use authorization in a healthy young woman with no past medical history. Other possible etiologies of her symptoms were ruled out, and she was treated successfully with steroids and plasma exchange.

Discussion

TM is a rare, acquired focal inflammatory disorder of the spinal cord in the absence of a compressive lesion. The most prevalent causes are demyelinating illnesses such as multiple sclerosis, neuromyelitis optica, infections, and vaccines. Systemic autoimmune diseases such as systemic lupus erythematosus and Sjögren's syndrome can damage the spinal cord in rare cases. (…) In our case, the MRI study demonstrated a long segment of increased signal throughout the spinal cord extending at least from C2-3 up to the thoracic spine, suggestive of TM. The role played by the SARS-CoV-2 vaccine, in this case, was found to be significant after ruling out other causes such as connective tissue disorders, vasculitis, infectious etiology, and multiple sclerosis. Acute TM affects between 1 to 8 million people per year, with a peak occurrence between the second and fourth decade of life. Based on a systematic review of PubMed, EMBASE, and DynaMed journals published between 1970 and 2009, a total of 37 cases of vaccine-associated TM is 3.70, which is within the range predicted in the general population of the United States.

The idea of autoimmunity, where antibodies and T cells respond cross-reactively to central and peripheral nervous system neural epitopes, is emphasized in the hypothesis for vaccine-induced neuroinflammatory disease. The "Molecular Mimicry" concept emphasizes that vaccination might cause autoimmune disease by microbial pathogen proteins similar to human proteins. Only with the oral poliovirus vaccination, a pathogenic causal link for TM was identified. A common denominator among vaccines such as an adjuvant may play a role in the pathogenesis of TM. According to Vaccine Adverse Event Reporting System (VAERS), 254 (2.69%) of the 9442 adverse events following immunization recorded in association with Pfizer-BioNTech, Moderna, and Johnson & Johnson's COVID-19 vaccines were neurological, with nine cases of TM reported in VAERS]. Furthermore, two ATM serious adverse events were reported with the ChAdOx1 nCoV-19 (recombinant) vaccine trials. The SARS-CoV-2 structural surface vector glycoprotein antigen (spike protein; nCoV-19) gene is included in a replication-deficient chimpanzee adenoviral ChAdOx1 vaccine (AZD1222). The antigen may also be present in the COVID-19 vaccination AZD1222, or its chimpanzee adenovirus adjuvant could be a possible trigger leading to ATM. Johnson & Johnson's COVID-19 vaccine incorporates the adenovirus, a prevalent cause of respiratory illnesses. The adenovirus's DNA is altered to form a critical component of the SARS-CoV-2 virus particle, to which the body responds with an immunological response. This could be a possible immunological trigger for ATM. To our knowledge, this is the first reported longitudinally extensive TM following the SARS-CoV-2 vaccine with the lesion of TM extending for more than three vertebral segments in length. Currently, there are no standard guidelines to treat TM secondary to the COVID-19 vaccine. Our patient was treated with intravenous steroids and plasma exchange and showed significant improvement in her symptoms.

Conclusions

The COVID-19 vaccines were approved for emergency use based on phase 3 clinical efficacy data and they have to go through post-marketing surveillance. As mass immunization continues across the world, adverse events are expected to be increasingly reported. Numerous COVID-19 vaccine-related adverse events involving the nervous system were described in the available literature; however, TM and Bell's palsy have not been specifically reported. The physicians should be aware of this adverse effect after Johnson and Johnson's COVID-19 vaccination and maintain a high index of suspicion in patients coming with typical symptoms of TM after receiving the vaccine, report it, and treat it immediately.

NEUROMYELITIS OPTICA IN A HEALTHY FEMALE AFTER SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 MRNA-1273 VACCINE

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8516014/

Introduction

Neuromyelitis optica spectrum disorder (NMOSD) is an autoimmune process characterized by severe demyelination affecting the optic nerve and spinal cord. Longitudinally extensive transverse myelitis (LETM) is its most specific presentation, which includes inflammation of the gray matter over three or more contiguous vertebral bodies. We present the case of a 46-year-old female, healthy at baseline, who developed bilateral lower-extremity weakness and urinary retention following the first dose of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) mRNA-1273 vaccine. Her presentation was consistent with NMOSD and thought to be triggered by the vaccine.

Discussion

NMOSD is a disease characterized by severe demyelination affecting the optic nerve and spinal cord. This process is facilitated by antibodies that attack aquaporin water channels and lead to complement-mediated destruction and subsequent demyelination. AQP4 is the most common aquaporin channel in the brain of mammals. The areas of the central nervous system that are most commonly affected by NMOSD are those where AQP4 channels are abundantly expressed. These regions and their correlated pathologies include the optic nerve (optic neuritis), spinal cord (LETM), dorsal medulla (area postrema syndrome), brainstem (acute brainstem syndromes), and the thalamus/hypothalamus (acute diencephalic syndromes such as narcolepsy). (…) Based on the affected region, symptoms of NMOSD can include intense itching, paresthesia, dysesthesia, pain, seizures, headaches, bladder dysfunction, hyperthermia, galactorrhea, depression, suicidal ideation, and tonic spasms consisting of brief, recurrent and painful episodes of increased muscle tone with abnormal posturing of the affected limb. LETM is the most specific form of presentation of NMOSD, which includes inflammation affecting the central gray matter, extending over three or more contiguous vertebral bodies. (…)

The goals of treatment are to suppress inflammation, minimize central nervous system damage, and improve long-term neurological function. (…) Traditional secondary prevention includes immunosuppressant therapy, such as azathioprine or mycophenolate mofetil. (…)

Considering the temporal association between administration of the vaccine, onset of patient's symptoms, and previous reports of post-vaccination NMOSD, we have strong evidence to conclude that this patient's NMOSD was triggered by the SARS-CoV-2 mRNA-1273 vaccine. Not only did she have multiple symptoms consistent with this disorder, including pain, paresthesia, weakness, and urinary retention, but she also had the most specific form of its presentation: LETM. Her negative AQP4-Ab serology made her diagnosis more challenging as she only had one core clinical criterion. However, her MRI results of hyperintensity spanning the gray matter of C6-T2 are the most specific finding of NMOSD, the extensive work-up performed excluded alternative diagnosis, and her symptoms improved after initiation of corticosteroids. Therefore, we are confident that this was a case of post-vaccination NMOSD. Immunosuppressants were not initiated during this acute attack as the discussion about secondary prevention was more appropriate in the outpatient setting.

Conclusions

This case report provides crucial information on the possible adverse effects associated with the SARS-CoV-2 mRNA-1273 vaccine. Post-vaccination myelitis and other neurologic reactions are rare. Nonetheless, early recognition is important as treatment can sometimes curtail long-term disability. Considering the novelty of these vaccines, there is a paucity of literature on this topic. NMOSD is a severe and rapidly progressive disease that can result in profound disability, including loss of vision, paralysis, and seizures. Therefore, a high degree of suspicion is key to accurately diagnose and intervene in order to prevent long-term neurological complications.

POST-COVID-19 VACCINE ACUTE HYPERACTIVE ENCEPHALOPATHY WITH DRAMATIC RESPONSE TO METHYLPREDNISOLONE: A CASE REPORT

SOURCE: https://www.sciencedirect.com/science/article/pii/S2049080121007536

Abstract

Since introducing the SARS-CoV-2 vaccination, different adverse effects and complications have been linked to the vaccine. Variable neurological complications have been reported after receiving the COVID-19 vaccine, such as acute encephalopathy.

Case presentation

In this report, we describe a 32-year-old previously healthy man who developed acute confusion, memory disturbances, and auditory hallucination within 24 hours from getting his first dose of the COVID-19 Moderna vaccine. EEG showed features of encephalopathy, CSF investigations were nonspecific, and MRI head did not depict any abnormality. He received five days of ceftriaxone and acyclovir without any benefit.

Discussion

Extensive workup for different causes of acute encephalopathy, including autoimmune encephalitis, was negative. Also, our patient improved dramatically after receiving methylprednisolone, supporting an immune-mediated mechanism behind his acute presentation. Accordingly, we think the COVID-19 vaccine is the only possible cause of our patient presentation, giving the temporal relationship and the absence of other risk factors for encephalopathy.

Conclusion

The clinician should be aware of the possible neurological complications of the different COVID-19 vaccines. Further research is needed to clarify the pathophysiology of such complications.

AUTOIMMUNE ENCEPHALITIS FOLLOWING CHADOX1-S SARS-COV-2 VACCINATION

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8630512/

Introduction

ChAdOx1-S (Covishield™/Vaxzevria, Astra-Zeneca) is the main vaccine recommended for mass national immunization program in the Republic of Korea against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and has been administered since March 2021. In addition to mild side effects including pain at the injection site, myalgia, arthralgia, and headache, a serious adverse effect involving vaccine-induced thrombotic thrombocytopenia (VITT) with vascular complications has been reported after administration of this adenovector-based SARS-CoV-2 vaccine [1, 2]. Rarely, autoimmune disease such as Guillain-Barré syndrome (GBS) has also been associated with ChAdOx1-S vaccination [3, 4]. However, as a post-vaccination phenomenon, autoimmune encephalitis (AE) has yet to be reported in the literature. Herein, we describe a patient who developed autoimmune encephalitis the day after the second dose of ChAdOx1-S vaccination with progressive cognitive worsening in a 4-week period.

Discussion

The neurological complications of SARS-CoV-2 infection extend across the entire nervous system including cerebrovascular disorders, post-infectious encephalopathies/encephalitis, and peripheral nervous system manifestations, typically GBS and its variants. In addition, SARS-CoV-2 vaccine also has been reported to be associated with autoimmune disease such as Guillain-Barré syndrome (GBS).

In this report, we describe a previously healthy patient who developed autoimmune encephalitis the day after the second dose of the ChAdOx1-S vaccine, followed by recurrent seizures and progressive cognitive decline during a 4-week period. Although we evaluated the validity of this report using the Naranjo Adverse Drug Reaction Probability Scale, which corresponded to the total score of four with “possible” causality, it cannot be decisively confirmed owing to the lack of any identified direct causative biomarker or antibody. However, considering the low prevalence of autoimmune encephalitis in the general population, an estimated prevalence of 13.7/100,000, as well as the immediate temporal relationship between the vaccination and the development of autoimmune encephalitis in a previously healthy individual, the diagnosis of vaccine-induced AE appears plausible.

Acute disseminated encephalomyelitis (ADEM) was reported after SARS-CoV-2 vaccination using inactivated SARS-CoV-2 (Vero Cells, Beijing Institute of Biological Products Co., Ltd., Beijing, China). However, our case differs from typical ADEM in several aspects. The initial MRI lesion in our patient was restricted to the medial temporal and insular cortical ribbons excluding white matter or basal ganglia, which are the typical MRI features of limbic encephalitis, while most of ADEM shows several bilateral confluent white matter lesions in both cerebral hemispheres early in the course. Furthermore, the follow-up MRI demonstrated the encephalomalacic changes in the left temporal lobe suggesting axonal destruction rather than demyelinating disease such as ADEM. A positive oligoclonal IgG band and a negative MOG antibody test in our patient also favored the diagnosis of AE rather than ADEM.

Recently, one case-series study which investigated patients with SARS-CoV-2 infection and neuropsychiatric symptoms raised the possibility of the central nervous system autoimmunity of the SARS-CoV-2 antibody based on the discovery of anti-SARS-CoV-2 IgG in the CSF.

In conclusion, our findings suggest the potential possibility of AE following vaccination with ChAdOx1-S. Further case reports are needed to confirm this association.

SEVERE AUTOIMMUNE HEMOLYTIC ANEMIA FOLLOWING RECEIPT OF SARS-COV-2 MRNA VACCINE

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8661722/

Case Presentation

Here we present a novel case of a young woman who developed life-threatening autoimmune hemolytic anemia (AIHA) after her first dose of a SARS-CoV-2 mRNA vaccine. Notably, initial direct antiglobulin testing was negative using standard anti-IgG reagents, which are “blind” to certain immunoglobulin (IgG) isotypes. Further testing using an antiglobulin reagent that detects all IgG isotypes was strongly positive and confirmed the diagnosis of AIHA. The patient required transfusion with 13 units of red blood cells, as well as treatment with corticosteroids, rituximab, mycophenolate mofetil, and immune globulin.

Discussion

Autoimmune hemolytic anemia (AIHA) is a rare disorder characterized by the production of autoantibodies against RBC antigens, leading to hemolysis. AIHA can either be primary or occur secondary to rheumatologic conditions, lymphoproliferative disorders, infection, or medications. In the present case, there was a strong clinical suspicion that the SARS-CoV-2 mRNA vaccine was the inciting event for the AIHA based on the chronology of events, the atypical autoantibody profile, and the absence of other causes. (…)

There have been cases of AIHA reported following vaccination to other pathogens. Vaccines activate both the humoral and cell-mediated arms of the adaptive immune system by production of effector and memory cells. The mechanism underpinning vaccine-induced autoimmunity is not clear, but it may be due to molecular mimicry and the development of auto-reactive T cells in a susceptible host.

The cornerstone of treatment for AIHA is immunosuppression, with corticosteroids serving as first-line therapy in warm and mixed AIHA.1 Second-line therapy for AIHA includes rituximab, a monoclonal antibody directed at CD20. In a meta-analysis of 409 patients with AIHA refractory to corticosteroids, the overall response rate to rituximab was 73%.10 Third-line agents include azathioprine, cyclosporine, cyclophosphamide, and MMF. IVIG may be used in combination with other treatments, especially in cases of severe hemolysis. Splenectomy remains an option as well, with an approximately 80% response rate, with 20%–50% of patients achieving sustained response.1 Clinical trials are ongoing evaluating the safety and efficacy of novel treatments for AIHA, including the Syk inhibitor fostamatinib (clinicaltrials.gov NCT04138927), Bruton tyrosine kinase inhibitor ibrutinib (NCT04398459), and neonatal Fc receptors (NCT04119050).

Our patient developed a robust AIHA 1 week after receiving her first dose of the SARS-CoV-2 mRNA vaccine. Although causation cannot be proven, the temporal relationship in the absence of an alternative cause argues in favor of de novo vaccine-induced AIHA.

Conclusion

As efforts to administer SARS-CoV-2 vaccines continue globally, clinicians must be aware of potential autoimmune sequelae of these therapies.

BELL'S PALSY AND SARS-COV-2 VACCINES—AN UNFOLDING STORY

SOURCE: https://www.sciencedirect.com/science/article/pii/S1473309921002735

Findings

Following the documentation of a case of Bell's palsy associated with vaccination, we were contacted by patients and colleagues from Canada, Australia, Europe, the UK, and United Arab Emirates. Questions raised were whether mRNA vaccine recipients are at increased risk of developing Bell's palsy, and what to recommend to individuals with a history of Bell's palsy.

In their Comment, Al Ozonoff and colleagues considered key statistical and epidemiological aspects of SARS-CoV-2 vaccine trial safety data regarding the onset of facial paralysis. Here, we offer a different interpretation of their findings and statistical consideration of risks associated with mRNA and non-mRNA SARS-CoV-2 vaccines.

Despite geographical and seasonal variations, the generally agreed incidence of Bell's palsy is 15–30 cases each year per 100 000 population. Ozonoff and colleagues rightly state that the predicted 12-month (annual) incidence of Bell's palsy inferred from mRNA vaccine trials is higher than that reported during the 2-month observation period of these studies. They concluded that the observed incidence of Bell's palsy in the mRNA vaccine arms was 3-5 to seven times higher than expected in the general population. However, safety data were collected for participants with a median follow-up of 2 months after the second dose; therefore, the data refer to an overall observation period of approximately 12 weeks from dose one. Given this, and considering Bell's palsy as the possible outcome of individual doses, the observed incidence in the mRNA vaccine trials would be roughly 1-5 to three times higher than in the general population (table).

The numerical imbalance reported with mRNA vaccine trials was not seen in the Oxford-AstraZeneca and Johnson & Johnson phase 3 studies using more traditional virus-based technology. Examination of adverse event data from the Yellow Card scheme in the UK and from the EU EudraVigilance database might help clarify this matter. As of March 21, the Yellow Card-reported frequency of facial paralysis or paresis and facial nerve disorder after any dose was close to 23 per million with the Pfizer-BioNTech vaccine and 13 per million with the Oxford-AstraZeneca vaccine. Excluding reports of facial paralysis cross-listed with cerebrovascular accident, EudraVigilance data indicate a much higher frequency of facial paralysis after the Pfizer-BioNTech vaccine than after the Oxford-AstraZeneca vaccine (497 vs 56 cases or 13-6 vs 4-1 per million doses as of April 3). The risk of developing facial paralysis could be two to three times higher in individuals receiving mRNA vaccines than in those receiving traditional vaccines. These findings should be considered when selecting a vaccine for patients with a history of Bell's palsy.

BELL'S PALSY FOLLOWING COVID-19 VACCINATION: A CASE REPORT

SOURCE: https://www.sciencedirect.com/science/article/pii/S217358082100122X

Findings

On 7 January 2021, the Spanish Navy's Health Services Directorate for Bahía de Cádiz, in Rota, started the first COVID-19 vaccination campaign for navy personnel. We administered the Pfizer BNT162b2 mRNA vaccine, officially approved by the European Medicines Agency on 21 December 2020. Commercialisation of the Moderna vaccine was subsequently approved on 6 January 2021; this vaccine has a very similar action mechanism to that of the Pfizer vaccine, using mRNA.

Both vaccines are associated with adverse reactions involving the orofacial region (one case in 1000 vaccinated individuals), such as Bell's palsy; however, this observation was not included in information targeted at patients in the United States and Canada. A literature search confirmed that rare cases of Bell's palsy were observed in the phase 3 trial of the BNT162b2 vaccine, with 4 cases among patients receiving the vaccine and none in the placebo group. However, as incidence did not exceed that observed in the general population, no clear association was established between vaccination and Bell's palsy.

Between 7 January and 18 March 2021, our department administered a total of 1757 doses of the Pfizer-BioNTech mRNA vaccine, fully vaccinating 877 individuals with both doses. Three different batches of the vaccine were used. We present the case of a patient who developed Bell's palsy several days after being vaccinated against COVID-19. The patient consented to the publication of the personal information included in this article. The patient was a 50-year-old white man with no relevant medical history, who received the first dose of the Pfizer mRNA vaccine on 9 February 2021. He reported local pain at the injection site on the second and third days after inoculation, and general fatigue on days 4 and 5; these are common adverse effects of the vaccine. On 28 February, 9 days after administration of the first dose, he noticed muscle weakness on the left side of the face, preventing him from drinking fluids, and visited the emergency department at Hospital General de Puerto Real (Cádiz). He presented facial droop, effacement of the nasolabial fold, and flaccidity on the left side of the face. Physical examination revealed complete paralysis of the left side of the face (the patient was unable to raise his eyebrow, close his left eye, or lift the labial commissure); he also presented effacement of frontal wrinkles. The emergency department diagnosed the patient with facial palsy and referred him to the outpatient neurology department (Fig. 1).

The patient had no history of trauma or systemic infection, and presented no skin eruptions compatible with herpes zoster infection or cutaneous abnormalities compatible with skin cancer. He also had not suffered a tick bite. A brain MRI study (axial, sagittal, and coronal planes; T1- and T2-weighted and FLAIR sequences) ruled out intracranial space-occupying lesions and ischaemic events. The patient had no history of previous or recent SARS-CoV-2 infection. The neurology department confirmed the diagnosis of acute unilateral Bell's palsy. (…)

At 21 days, after completing the course of corticotherapy, paresis began to improve, although the patient continued to have difficulty fully closing the eye and raising the labial commissure; this progression is compatible with the course of the disease. (…)

[Bell's Palsy] is characterised by rapidly progressive (less than 72 hours), unilateral, and generally self-limited symptoms that resolve within 3-6 months in 80% of cases. Its aetiology is uncertain and it may be triggered by numerous causes.

While we are unable to demonstrate that Bell's palsy was an adverse reaction to the Pfizer-BioNTech mRNA vaccine in our patient, an increasing body of evidence obliges us to reflect on the close relationship between both events. Colella et al.9 report a case of Bell's palsy with similar characteristics to our own case in a patient who had received the same vaccine. Therefore, we consider that it would be beneficial for the healthcare authorities to emphasise the importance of monitoring patients developing Bell's palsy after the administration of mRNA vaccines.

BELL'S PALSY AFTER 24 HOURS OF MRNA-1273 SARS-COV-2 VACCINE

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8312995/

Abstract

(...) Currently, two mRNA vaccines are being offered internationally, BNT162b2 and mRNA-1273. In randomized trials of these vaccines, the incidence of Bell's palsy in the vaccinated group does not statistically exceed the placebo group. The FDA recommends increased surveillance for Bell's palsy as a potential side effect with the administration of the vaccines among larger populations globally. There have been a few case reports of Bell's palsy associated with mRNA vaccines. Type I interferons have been proposed as the potential mechanism linking mRNA COVID-19 vaccines to Bell's palsy. Here, we report the case of a 36-year-old previously healthy patient who developed symptoms of Bell's palsy along with left-arm numbness, tingling, and subjective weakness masquerading as a subacute stroke after receiving the second dose of the mRNA-1273 vaccine. CT and MRI of the brain were unremarkable. He was discharged home with a diagnosis of Bell's palsy and improved on follow-up. mRNA COVID-19 vaccines may be considered a risk factor for Bell's palsy.

Discussion

Bell's palsy, also known as idiopathic facial nerve paralysis, is considered to be the most common cause of acute facial paralysis of spontaneous origin. Potential contributors to the development of Bell's palsy include immune, infective, and ischemic mechanisms; however, the exact cause remains unclear. Reactivation of herpes simplex virus infection centered around the geniculate ganglion is suggested as a possible cause.

The occurrence of Bell's palsy has been linked to vaccine administration in the past. A matched case-control study and case series in 2000-2001 found an increased incidence of Bell's palsy among the receivers of intranasal inactivated influenza vaccine (with an odds ratio of 84%). This phenomenon was thought to be due to the interaction of heat-labile Escherichia coli toxin found in the vaccine with the facial nerve. Adverse reports of Bell's palsy have also been published after the administration of the meningococcal conjugate vaccine.

In the published data regarding the mRNA-1273 vaccine, among the 30,351 volunteers who participated in the trial, three cases of Bell's palsy were reported in the vaccinated group on days 22, 28, and 32 days after vaccination. One incident occurred in the placebo group 17 days after vaccination. The trial concluded that the slight excess of Bell's palsy in this trial and the BNT162b2 vaccine trial raised a concern that it may be more than a chance event, and this possibility bears close monitoring. A retrospective study with 455 participants found three cases of Bell's palsy and one with body tingling in individuals who received the first dose of the BNT162b2 vaccine.

Other COVID-19 vaccine trials have also reported Bell's palsy as an adverse event. The single-dose Ad26.COV2.S vaccine used recombinant, replication-incompetent human adenovirus type 26 (Ad26) vector. In a clinical trial of the Ad26.COV2.S vaccine, three cases of Bell's palsy were reported in the vaccine group compared with two cases in the placebo group. The observed frequency of Bell's palsy in the vaccine and control group was consistent with the expected background rate in the general population. Nishizawa et al. reported a case of Bell's Palsy after receiving the Ad26.COV2.S vaccine.

Soeiro et al. proposed type I interferons as the potential mechanism linking mRNA COVID-19 vaccines to Bell's palsy. Therefore, the mRNA COVID-19 vaccine should be considered as an additional risk factor for Bell's palsy.

Conclusions

Data from vaccine trials of mRNA covid vaccines, BNT162b2 and mRNA-1273, suggest that there is an increased propensity of Bell's palsy cases in the vaccinated group. However, the causal relationship between the mRNA vaccine and Bell's palsy development needs to be further investigated. Our case highlights the importance of vaccine history in patients presenting to the emergency department with Bell's palsy. COVID-19 mRNA vaccines can be considered as an additional possible risk factor in the etiology of Bell's palsy.

NEURO-COVAX: AN ITALIAN POPULATION-BASED STUDY OF NEUROLOGICAL COMPLICATIONS AFTER COVID-19 VACCINATIONS

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10610846/

Abstract

In this Italian population-based study, we aimed to evaluate the neurological complications after the first and/or second dose of COVID-19 vaccines and factors potentially associated with these adverse effects.

Introduction

When we examine under a magnifying glass the potential neurological complications post-vaccination, the first concern is dated from September 2020, when AstraZeneca/Oxford University reported severe inflammation of the spinal cord. In May 2021, the American Neurology Academy provided the first report on the common neurological complications after COVID-19 vaccines. In December 2021, a large population-based study identified rare neurological adverse events after the first dose of the ChAdOx1nCoV-19 and BNT162b2 vaccines. Severe and unexpected post-vaccination complications have also recently been detected. They include cerebral venous sinus thromboses occurring especially in females after adenovector-based vaccination, as well as Guillain-Barré syndrome, facial palsy, other neuropathies, encephalitis, meningitis, myelitis and autoimmune disorders. (…) However, little is yet known about the neurological complications after both doses of COVID-19 vaccines, as well as about their nature. Finally, the exact pathogenesis of vaccine-associated adverse events remains under debate. Several mechanisms based on the innate immune response and miming the reactivity to the viral infection have been recently proposed. This is the case for headaches that are secondary to SARS-CoV-2 infection. Patients with long COVID headaches, especially in an acute phase of the disease, can manifest a persistent immune system activation with evidence of altered blood levels of cytokines and interleukins.

Discussion

This large population-based study in Italy investigated the neurological complications associated with first and second doses of three COVID-19 vaccines in use in the hub of Novegro (Milan, Lombardy). We identified several findings that were of clinical relevance to public health and scientific interest for clinicians and researchers. Firstly, we observed an increased risk of neurological adverse events in females, and for the adenovirus ChAdOx1nCov-19 vaccine, a trend for mRNA vaccines such as mRNA-1273 and BNT162b2. In line with this, a significant association between neurological symptoms following ChAdOx1nCov-19 and mRNA-1273 vaccination compared to BNT162b2 is also reported. Secondly, in the symptomatic vaccinated group, we identified a neurological risk profile that is specific for each vaccine. There is an increased risk for the ChAdOx1nCov-19 vaccine of tremors, insomnia, tinnitus, muscle spasms and headache; an increased risk for the mRNA-1273 vaccine of taste and smell alterations, vertigo, diplopia, sleepiness, parethesias and dysphonia; then, an increased risk for the BNT162b2 vaccine of cognitive fog. Finally, defining the symptomatic group, we found that over 40% of the subjects showed comorbidities in their clinical histories. (…)

Conclusions

This study identified a specific neurological risk profile for each vaccine and a clinical profile for those more vulnerable to develop neurological complications after COVID-19 vaccines. Clinicians should be aware that several neurological complications may commonly occur after COVID-19 vaccines, but in most cases, these have a benign nature. On the other hand, caution should be used when administering COVID-19 vaccines to vulnerable people, such as to those who suffer from allergies. We strongly believe that our findings are relevant for public health regarding the safety of vaccines in a large cohort.

Bleeding and Hemorrhagic Disorders

Intracerebral Hemorrhage	Bleeding within the brain tissue, often caused by a ruptured blood vessel. It can lead to brain damage and requires immediate medical attention.
Hemorrhage	Excessive bleeding, whether internal or external, and can range from minor to life-threatening, depending on the cause and amount of blood lost.
Bleeding Episodes	Individual instances of blood loss from the body, often recurring and associated with various medical conditions, injuries, or surgeries.

INTRACEREBRAL HEMORRHAGE ASSOCIATED WITH VACCINE-INDUCED THROMBOTIC THROMBOCYTOPENIA FOLLOWING CHADOX1 NCOVID-19 VACCINE IN A PREGNANT WOMAN

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8561298/

Findings

The ChAdOx1 nCoV-19 (Oxford-AstraZeneca) vaccine consists of a replication-deficient chimpanzee adenoviral vector containing the SARS-CoV-2 structural surface glycoprotein spike antigen gene. No signal for increased thrombotic events was detected in clinical trials of this vaccine involving 23,848 participants, which has now been administered to more than 34 million people worldwide. As reported to date, 20.8 million doses of the ChAdOx1 nCoV-19 vaccine have been applied in Brazil. ChAdOx nCoV-19 has been associated with vaccine-induced thrombotic thrombocytopenia (VITT), a rare but serious adverse event. The potential underlying associated mechanism is the formation of anti-heparin/platelet factor (PF4) antibodies, but risk factors other than young age remain unclear. The immune-driven disease resembles heparin-induced thrombocytopenia (HIT) because platelet-activating antibodies recognize multimolecular complexes between cationic PF4 and anionic heparin, but classically there is no heparin exposure in VITT. So far, the incidence of VITT is around one case per 100,000 exposures to the ChAdOx1 nCoV-19 vaccine. Clinically, it is characterized by thrombocytopenia and thrombosis in unusual sites, particularly cerebral venous or splanchnic-vein thrombosis. Cerebral venous sinus thrombosis (CVST), a life-threatening event, was described in 72% of the VITT reports. Clinical trials did not include pregnant women, and the available data came from accidental pregnancies. Pregnant patients with COVID-19 are more likely to die or need intensive care compared with non-pregnant persons of reproductive age. (...)

We present the first report of VITT following ChAdOx1 nCOVID-19 vaccination in a pregnant woman. Despite the lack of image verification of cerebral thrombosis, clinical features were suggestive. Initial brain CT may be negative for CVST in about 30% of cases. Besides that, thrombosis was observed in placental vessels. The constellation of signs and symptoms suggests VITT diagnosis complicated by intracranial hemorrhage with a fatal outcome both to fetus and mother. Three independent descriptions of 39 persons presenting VITT after vaccination with ChAdOx1 nCoV-19 revealed a vast majority being women younger than 50 years of age and some of them receiving estrogen-replacement therapy or oral contraceptives. Nevertheless, most of the participants did not have preexisting risk factors for thrombosis. Patients presenting VITT have unusually severe thrombocytopenia, increased frequency of disseminated intravascular coagulation, and atypical thrombotic events. Serum from these patients shows a strong reactivity on the PF4–heparin ELISA and activates platelets in the presence and absence of heparin, but a high concentration of heparin completely inhibits the effect, as occurred in our case. (…)

Stroke affects 30 per 100,000 pregnancies, with ischemia, CVST, and hemorrhage causing roughly equal numbers and the highest risk in peripartum and postpartum. However, it is unclear if the pregnancy itself could increase the risk for thrombotic events following ChAdOx1 nCov-19 vaccination with the formation of anti-PF4 antibodies. (...)

This case report draws attention to this possible severe vaccine side effect among pregnant women and the challenges related to an early diagnosis. When symptomatic, pregnant women experience difficulties diagnosing VITT due to avoidance of screening methods involving radiation and presenting features possibly related to pregnancy, such as thrombocytopenia. The presence of persistent headache and thrombocytopenia within 30 days of vaccination should raise the suspicion of VITT. (...)

At least five countries had instituted limitations primarily based on age on which patients should receive the ChAdOx1 nCoV-19 vaccine, and Brazil recently temporarily suspended the administration of this vaccine in pregnant women. Those either affected by VITT or under investigation for this complication should not receive a second ChAdOx1 nCoV-19 vaccine. Physicians should have a low threshold for recognizing VITT signs and symptoms and requesting ELISA testing for PF4–polyanion antibodies and confirmatory functional tests. Although rare, VITT is a new phenomenon with devastating effects for otherwise healthy young adults, and its association with COVID-19 vaccination requires a thorough risk-benefit analysis especially for pregnant women.

INTRACEREBRAL HEMORRHAGE DUE TO VASCULITIS FOLLOWING COVID-19 VACCINATION: A CASE REPORT

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8594320/

Abstract

Several vaccines have been approved worldwide for the prevention of morbidity and mortality against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). However, the development of these vaccines has raised concerns regarding their adverse effects. Herein, we report the first case of intracerebral hemorrhage (ICH) due to vasculitis after the first dose of mRNA vaccine (BNT162b2, Pfizer/BioN-Tech). Although this case cannot demonstrate a direct relationship between COVID-19 vaccination and vasculitis, the clinical and histological features of this patient are highly consistent with the adverse effects of COVID-19 vaccine.

Discussion

During the COVID-19 pandemic, several vaccines against SARS-CoV-2 have been approved after the demonstration of safety and efficacy. However, several adverse effects have also been reported. Typical reactogenicity included mild-to-moderate pain at the injection site, fatigue, headache, and fever. In addition, some rare cases of vaccine-induced CNS diseases have been reported. Particularly, stroke due to thromboembolism after COVID-19 vaccination is a major concern. The mechanism of vaccine-induced thromboembolism is usually the same as that of SARS-CoV-2, which is a hypercoagulable state. However, some rare cases of thrombotic thrombocytopenia as the cause of stroke have also been demonstrated. In these cases, venous thrombosis may appear more frequently than arterial thrombosis. Our study is the first to report a case of ICH due to vasculitis following COVID-19 vaccination.

Vasculitis after COVID-19 vaccination has been reported in different dermatological areas. A recent study demonstrated that the frequencies of vasculitis within approximately two weeks after the first dose of Pfizer (New York, NY, USA)-BioNTech (Mainz, Germany) (BNT162b2) and Moderna (mRNA-1273) vaccine were 2.9% and 0.7%, respectively. Pathological findings include small vasculitis, characterized by fibrin deposits, fibrinoid necrosis associated with neutrophil infiltration of the vessel walls, and leukocyte destruction. The pathogenesis of vasculitis following vaccination remains unclear, although an autoimmune mechanism mediated by vaccine proteins has been proposed. Therefore, similar to influenza vaccination, the COVID-19 vaccination may result in vasculitis in several organs.

Clinicopathological differential diagnoses include hypertensive cerebral hemorrhage, amyloid angiopathy, angiitis of the central nervous system (ACNS), secondary vasculitis, and an adverse effect of the COVID-19 vaccine. The patient's blood pressure was within normal limits, and there was no history of hypertension. Amyloid angiopathy is associated with aging, and amyloid deposits are found mainly in the small arteries and arterioles. Although amyloid deposition may be accompanied by granulomatous vasculitis, there was no amyloid deposition or granuloma in the vessel wall in the present case. In typical ACNS, small- to medium-sized arteries are involved that present with histological findings of granulomatous vasculitis, necrotizing polyarteritis, and lymphoplasmacytic vasculitis. However, the histological findings observed in this case were different. Lastly, secondary vasculitis is an incidental histological finding in any organ and is usually associated with necrosis or viral/bacterial infection, including in COVID-19. Indeed, SARS-CoV-2 itself induces a hyperinflammatory response in endothelial cells, which causes vasculitis in the kidneys, heart, lungs, and small bowel. However, no necrosis or pyogenic inflammation was observed in the cerebral tissue of this patient. Although there is no direct proof that vasculitis was caused by the vaccination, the clinical and histologic features of this patient are highly consistent with an adverse effect of the COVID-19 vaccine. Thus, further studies are necessary to ensure the safety of COVID-19 vaccination.

INTRACEREBRAL HEMORRHAGE DUE TO THROMBOSIS WITH THROMBOCYTOPENIA SYNDROME AFTER VACCINATION AGAINST COVID-19: THE FIRST FATAL CASE IN KOREA

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8352786/

Abstract

Vaccination with an adenoviral vector vaccine against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) can result in the rare development of thrombosis with thrombocytopenia mediated by platelet-activating antibodies against platelet factor 4 (PF4). This is a life-threating condition that may be accompanied by bleeding due to thrombocytopenia with thrombosis of the cerebral venous sinus or splanchnic vein. Herein, we describe the first fatal case of thrombosis with thrombocytopenia syndrome in Korea, presenting with intracranial hemorrhage caused by cerebral venous sinus thrombosis. A 33-year-old Korean man received the first dose of the ChAdOx1 nCoV-19 vaccination. He developed severe headache with vomiting 9 days after the vaccination. Twelve days after vaccination, he was admitted to the hospital with neurological symptoms and was diagnosed with cerebral venous sinus thrombosis, which was accompanied by intracranial hemorrhage. Thrombocytopenia and D-dimer elevation were observed, and the result of the PF4 enzyme-linked immunosorbent assay antibody test was reported to be strongly positive. Despite intensive treatment, including intravenous immunoglobulin injection and endovascular mechanical thrombectomy, the patient died 19 days after vaccination. Physicians need to be aware of thrombosis with thrombocytopenia syndrome (TTS) in adenoviral vector-vaccinated patients. Endovascular mechanical thrombectomy might be a useful therapeutic option for the treatment of TTS with cerebral venous sinus thrombosis.

Discussion

This is the first fatal case of TTS by vaccination against COVID-19 in Korea. In this case, the initial diagnosis was delayed at the primary clinic. At the time of admission to the emergency room, treatment was difficult because of extensive thrombosis with cerebral hemorrhage. In addition, platelet transfusion was performed before early recognition of TTS, resulting in poor prognosis. Adenoviral vector SARS-CoV-2 vaccines from AstraZeneca (ChAdOx1 nCoV-19, Vaxzevria) and Janssen (Ad26.COV2.S, JNJ-78436735) have been found to very rarely cause TTS. Antibodies related to PF4 induced by adenovector vaccination activate platelets, decrease platelet count, and cause thrombosis.3 (…) Although the incidence of TTS is low, it has very high mortality and morbidity, and early diagnosis and treatment are necessary for a good prognosis, clinicians need to raise awareness of TTS. According to a recently published animal model study, intravenous injection of ChAdOx1 nCov-19 triggers platelet-targeted autoimmunity in spleen, that may result TTS. Hence, safe intramuscular injection, with aspiration prior to injection, could be a potential preventive measure when administering adenovirus-based vaccines.

In the majority of cases of TTS, the site of thrombosis was the cerebral veins, and splanchnic vein thrombosis and pulmonary embolism were other common manifestations. Clinical presentations of CVT can be diverse and highly variable, ranging from the non-specific symptoms, such as headache or blurred vision, to coma. Ilyas et al.8 summarized a large number of case series of CVT; according to their report, headache was the most common presentation of CVT, which was followed by focal neurologic deficit, seizure, and altered mental status. Since these symptoms are highly likely to be confused with conventional adverse events that can occur after SARS-CoV-2 vaccination, diagnosis of TTS with CVT requires a high index of suspicion. (…) Crescendo-type progression of symptoms over a few days with a recent history of adenoviral vector SARS-CoV-2 vaccination raises a strong possibility of CVT, which should be followed by appropriate laboratory and imaging studies for the diagnosis of TTS. (…)

In conclusion, the diagnosis of CVT due to TTS has to be made with high suspicion because of its rapid and diverse clinical manifestations. Endovascular mechanical thrombectomy might be a useful therapeutic option for the treatment of TTS with CVT.

LARGE HEMORRHAGIC STROKE AFTER CHADOX1 NCOV-19 VACCINATION: A CASE REPORT

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8444739/

Abstract

The anti-COVID-19 vaccines are new, and we should be alert of potential adverse effects of them.

Results

A woman, 57 years old, took the first dose of the ChAdOx1 nCoV-19 vaccine and shortly thereafter presented mild systemic symptoms and started on aspirin. On day 5, she had a sudden onset of sweating and paleness, which has followed by left hemiparesis, vomiting, and somnolence. Computed tomography showed a large right deep frontal lobe parenchymal hematoma with the inundation of the entire ventricular system. Platelets count, fibrinogen, prothrombin time, and D-dimer were normal. Digital subtraction angiography did not show any signs of thrombosis or aneurysms in brain circulation.

Discussion

Brain hemorrhage in the context of VITT has been described, but primary hemorrhagic stroke following ChAdOx1 nCoV-19 vaccination in a patient without thrombocytopenia, coagulation disorder, or risk factors was not. It is worth noting that this case presents an atypical site and uncommonly large volume for stroke, which raises concerns about its pathogenesis. Data 3 suggested that, besides thrombosis, there might also be a greater risk of bleeding events related to that vaccine. Although we cannot claim causality in this report, it is important to keep surveillance on the adverse effects of vaccines.

Conclusions

Clinicians should be aware of cerebrovascular adverse effects of ChAdOx1 nCoV-19, including out-of-context of vaccine-induced immune thrombotic thrombocytopenia.

FATAL CEREBRAL HAEMORRHAGE AFTER COVID-19 VACCINE

SOURCE: https://tidsskriftet.no/en/2021/04/kort-kasuistikk/fatal-cerebral-haemorrhage-after-covid-19-vaccine

Abstract

The patient was a previously healthy woman in her thirties with headaches that developed one week after vaccination with ChAdOx1 nCoV-19. Three days later, her condition deteriorated rapidly, and she presented to the emergency department with slurred speech, uncoordinated movements and reduced consciousness. Symptoms progressed to left-sided hemiparesis and her level of consciousness deteriorated. Computed tomography (CT) of the head showed a large right-sided haemorrhage and incipient herniation. She was found to have severe thrombocytopenia 37 x 109/l, (ref 145 - 390 x 109/l). In spite of efforts to reduce intracranial pressure, the patient died the following day. Post mortem examination revealed antibodies to PF4, and fresh small thrombi were found in the transverse sinus, frontal lobe and pulmonary artery.

Interpretation: Severe thrombocytopenia and antibodies to PF4 make a diagnosis of vaccine-induced immune thrombotic thrombocytopenia (VITT) likely.

Discussion

The case study describes a young woman who had a fatal cerebral event following vaccination with AstraZeneca's ChAdOx1 nCoV-19 vaccine against COVID-19. At that point, no similar incidents or incidents of the same severity had been reported in Norway, and it was not a known adverse effect from the vaccine. However, rare cases of thrombocytopenia from COVID-19 vaccines using mRNA technology (3) were reported, and immunologically mediated thrombocytopenia was reported as a complication of COVID-19 (4).

A few days after this incident, Oslo University Hospital, Rikshospitalet reported multiple cases of severe blood clots and bleeding in patients who had received an identical vaccine. These patients also had low platelet counts, and in these cases a link was found between the events and the vaccine. Since then, the condition has been referred to as vaccine-induced immune thrombotic thrombocytopenia (VITT), which is characterised by low platelet counts, thrombus formation and antibodies to PF4. In light of this knowledge, new investigations were carried out, and our patient was also found to have a tendency towards thrombus formation with small thrombi in the transverse sinus, frontal lobe and pulmonary artery. Antibodies to PF4 were also detected. Overall, there is therefore a strong indication that this was a case of VITT. Retrospectively, it has to be asked whether the bleeding seen on the CT images represented a venous haemorrhagic infarction similar to that seen in several patients at Rikshospitalet, and whether the bleeding component may have been predominant as a result of VITT. A venous infarction might explain the patient's headache.

Experience with the condition is still limited, and this case study describes how a probable case of VITT can manifest itself clinically, radiologically and in the laboratory. An early symptom of this condition may be a headache, as in our patient, or visual disturbances, epileptic seizures, abdominal pain, chest pain, dyspnoea, or swelling or pain in the leg. Treatment is available, and the prognosis is significantly improved if the condition is identified before serious and irreversible complications occur.

Several countries are now reporting similar incidents after vaccination. The condition is rare, which is why it is important to shed light on these events. The vaccine is new and is an important part of the vaccine programme in many parts of the world. Following these incidents, the Norwegian Institute of Public Health issued a warning about potentially serious adverse effects of the vaccine. The AstraZeneca vaccine is now on hold in Norway. The government has appointed an expert panel to carry out a comprehensive risk assessment before any potential re-introduction of the vaccine. The Norwegian Institute of Public Health has reported that as the number of deaths from COVID-19 is now low in Norway, it seems that vaccination with the AstraZeneca vaccine entails a higher risk of death, particularly for younger people, than the risk of dying of the disease. Although thought-provoking, this was not known at the time our patient was offered the vaccine.

RETINAL HEMORRHAGE AFTER SARS-COV-2 VACCINATION

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8658415/

Abstract

To report retinal vein occlusion (RVO) and age-related macular degeneration (AMD)-related submacular hemorrhage developing after administration of SARS-CoV-2 vaccines, a single-center, retrospective observational case series was conducted. Clinical data including fundus photographs and optical coherence tomography (OCT) scans were reviewed. Twenty-three eyes of 21 patients were included with the median age at symptom presentation being 77 years (range: 51–85 years). Twelve eyes (52.2%) had submacular hemorrhage and 11 (47.8%) had RVO. Twelve patients (60.9%) had been vaccinated with the Pfizer vaccine (BNT162b2) and 8 with the AstraZeneca (ChAdOx1) vaccine. Sixteen patients (76.2%) experienced ocular disease exacerbation after the first vaccination and 4 (19.0%) after the second vaccination. The median visual acuity (logarithm of the minimal angle of resolution; logMAR) before symptom development was 0.76 (interquartile range: 0.27–1.23); the median logMAR at symptom presentation was 1.40 (interquartile range 0.52–1.70). The median time between vaccination and symptom exacerbation was 2.0 days (interquartile range: 1.0–3.0 days). Five patients (23.8%) underwent tests for hematological abnormalities, including the presence of anti-PF4 antibodies; all were negative. Further studies with larger patient group for evaluation of effect of SARS-CoV-2 vaccination on retinal hemorrhage are necessary.

Discussion

(…) Based on our data, there seems to be a temporal link between SARS-CoV-2 vaccination and RVO and AMD-related submacular hemorrhage. The median time from vaccination to symptom onset was 2 days, and all patients for whom the time of exacerbation was noted developed hemorrhage within 4 weeks of vaccination. Many of our patients were referrals from other centers (our institute is one of the largest tertiary centers in Korea), but the high number of patients with RVO and AMD-related submacular hemorrhage encountered within a short period (~4 months) indicates that these uncommon pathologies did not develop by chance. (…) Therefore, 21 cases in less than 4 months from among a limited number of vaccinated persons cannot be considered coincidental, especially given that this was a single-center study.

VITT and CVST developing after ChAdOx1 nCoV-19 vaccination have been confirmed in several reports; it was important to determine if our cases were associated with VITT, which is diagnosed when serum anti-PF4 Ab is detected by ELISA. Five of our patients (two vaccinated with BNT162b2 nCoV-19 and three with ChAdOx1 nCoV-19) underwent anti-PF4 Ab tests; all were negative. Thus, an association between VITT and retinal/submacular hemorrhage in our cohort seems unlikely. However, it may be that the anti-PF4 Ab titer was too low for clinical detection, although sufficiently high for thromboses to form in retinal vessels narrower than those of most other organs. (…)

Most systemic drug-related retinal toxicity is bilateral, but the RVO and AMD-related submacular hemorrhage in our patients were mostly unilateral. (…) RVO typically develops unilaterally, even in patients with diabetes and hypertension; the absence of bilateral RVO does not rule out a vaccine-induced condition. The pathogenesis of retinal hemorrhages developing after SARS-CoV-2 vaccination requires further study.

All patients had received either the adenoviral vector vaccine ChAdOx1 (AstraZeneca) or the mRNA vaccine BNT162b2 (Pfizer-BioNTech). This may be because these two vaccines were the mainstays of the government-driven, large-scale vaccination program initiated in South Korea. Both vaccines were associated with RVO and submacular hemorrhage. (…)

Further studies with larger patient groups for evaluation of direct mechanisms and the extent of the effect of SARS-CoV-2 vaccination on retinal hemorrhage are necessary. Nevertheless, clinicians should be aware of the possibility of such cases, and it may be necessary to adjust the treatment schedules of high-risk RVO and AMD patients.

ASSOCIATION BETWEEN CHADOX1 NCOV-19 VACCINATION AND BLEEDING EPISODES: LARGE POPULATION-BASED COHORT STUDY

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8406020/

Introduction

In Norway, five patients with thrombosis and thrombocytopenia were hospitalized 7 to 10 days after receiving the first dose of a chimpanzee adenovirus-vectored vaccine (expressing the SARS-CoV-2 spike protein) against COVID-19. In all patients, antibodies to platelet factor 4 was detected, suggesting a likely mechanism induced by vaccination. The same findings are reported from 9 patients in Germany. The cases may represent rare events, or they may be the tip of the iceberg, reflecting a more quantitative phenomenon. We hypothesized that if this mechanism were present in a larger proportion of vaccinated subjects, one would expect bleeding episodes. We had the opportunity to test this hypothesis in a large, ongoing, population-based cohort by comparing the prevalence of bleeding episodes in subjects receiving adeno-vectored vaccine with the prevalence in subjects receiving mRNA vaccine.

Methods

Using an ongoing large, population-based cohort study, more than 80 000 cohort participants were asked through electronic questionnaires about COVID-19 vaccination and potential side effects during weeks 11–13, 2021. The response rate was 58% (81267/138924). Among the vaccinated, 83% were female, 85% health care workers and 80% were aged 40–55 years.

The prevalence of self-reported episodes of skin, nose and gingival bleedings were compared after mRNA and adenovirus-vectored vaccination. Estimates were adjusted for age, sex, occupation, previous COVID-19 infection and chronic disease.

Results

Four of the 3416 subjects (0.2%) who were vaccinated with a single dose of mRNA vaccine reported skin bleeding as a side effect, as opposed to 163 of 5132 subjects (3.2%) vaccinated with a single dose of the adenovirus-vectored vaccine, OR (odds ratio) = 16.0 (95% confidence interval (CI) 7.5–34.1). Corresponding ORs for nose and gingival bleeding were 8.0 (4.0–15.8) and 9.3 (4.3–20.0), respectively.

Conclusions

These findings could potentially indicate that the adenovirus-vectored vaccine may lead to mild bleeding episodes in a larger proportion of vaccinated individuals, and not only in rare cases with documented thrombosis and thrombocytopenia. Studies are needed to understand the possible mechanisms behind these observations, and to establish or refute whether they share similarities with the severe thromboembolic bleeding complications.

BLOOD CLOTS AND BLEEDING EVENTS FOLLOWING BNT162B2 AND CHADOX1 NCOV-19 VACCINE: AN ANALYSIS OF EUROPEAN DATA

SOURCE: https://www.sciencedirect.com/science/article/pii/S0896841121000937

Abstract

The involvement of viruses and SARS-CoV-2 in autoimmune diseases is well known. The recent demonstration that ChAdOx1 nCoV-19 Covid-19 (AstraZeneca) vaccine (ChA) favors the production of anti-platelet factor 4 (anti-PF4) antibodies, blood clots, and thrombocytopenia raises the question of whether other anti-CoViD-19 vaccines favor the same patterns of events.

We assessed the frequency of severe adverse events (SAEs) documented in the EudraVigilance European database up to April 16, 2021 related to thrombocytopenia, bleeding, and blood clots in recipients of ChA compared to that of recipients of the BNT162b2 Covid-19 (Pfizer/BioNTech) vaccine (BNT).

ChA administration was associated with a much higher frequency of SAEs in each AE Reaction Group as compared with that elicited by BNT. When considering AEs caused by thrombocytopenia, bleeding and blood clots, we observed 33 and 151 SAEs/1 million doses in BNT and ChA recipients, respectively. When considering patients with AEs related to cerebral/splanchnic venous thrombosis, and/or thrombocytopenia, we documented 4 and 30 SAEs and 0.4 and 4.8 deaths/1 million doses for BNT and ChA recipients, respectively. The highest risk following ChA vaccination is in young people and, likely, women of reproductive age, as suggested by hypothesized scenarios.

In conclusion, the immune reaction promoted by ChA vaccine may lead to not only thrombocytopenia and cerebral/splanchnic venous thrombosis but also other thrombotic and thromboembolic SAEs. These events are not favored by BNT vaccine. Our study may help in the evaluation of the benefit/risk profile of the ChA vaccine considering the epidemic curve present in a country.

Conclusions

Differences among humans (genetics, epigenetics, sex, age) make some people much more prone to autoimmune reactions and more sensitive to rare AEs [48]. We here demonstrate a higher rate of thrombohemorrhagic events in ChA than BNT recipients. Specifically, CVT, SVT, and thrombocytopenia were more frequent in young people (18–24 years) and adult females (25–60 years). In BNT recipients, the frequency of thrombohemorrhagic events, including CVT, SVT, and thrombocytopenia, was not increased compared to that in the general population. Thus, vaccine-dependent production of the Spike protein may be a cofactor that favors serious thrombohemorrhagic adverse events, but it is not the only reason.

Our data may aid the evaluation of the risk-benefit ratio of the ChA vaccine taking into account the age and sex of the vaccinee, Covid-19 risk, and the depth of the pandemic in a particular country. The risk-benefit ratio of vaccines has to be evaluated more carefully in countries with low infection rate levels and when herd immunity is almost reached.

UNEXPECTED VAGINAL BLEEDING AND COVID-19 VACCINATION IN NONMENSTRUATING WOMEN

SOURCE: https://www.science.org/doi/10.1126/sciadv.adg1391

Abstract

The association between coronavirus disease 2019 (COVID-19) vaccination and vaginal bleeding among nonmenstruating women is not well studied. The Norwegian Institute of Public Health followed several cohorts throughout the pandemic and early performed a systematic data collection of self-reported unexpected vaginal bleeding in nonmenstruating women. Among 7725 postmenopausal women, 7148 perimenopausal women, and 7052 premenopausal women, 3.3, 14.1, and 13.1% experienced unexpected vaginal bleeding during a period of 8 to 9 months, respectively. In postmenopausal women, the risk of unexpected vaginal bleeding (i.e., postmenopausal bleeding) in the 4 weeks after COVID-19 vaccination was increased two- to threefold, compared to a prevaccination period. The corresponding risk of unexpected vaginal bleeding after vaccination was increased three- to fivefold in both nonmenstruating peri- and premenopausal women. In the premenopausal women, Spikevax was associated with at 32% increased risk as compared to Comirnaty. Our results must be confirmed in future studies.

Discussion

In agreement with our findings, two large studies from the United States and Sweden using health record systems found positive associations between COVID-19 vaccination and PMB. The risk of a PMB diagnosis was increased by 21 and 14% respectively, when compared to prevaccination periods. In our cohort, only 31% of women who reported a PMB sought medical care, and the proportion was even lower if the bleeding occurred after vaccination. Thus, lower risk estimates are expected from a diagnosis-based approach. Furthermore, the defined risk windows were longer than the 28 days in our study (i.e., 82 to 112 days).
Two of the abovementioned studies saw no clear difference in bleeding reports according to vaccine type. However, the Spikevax vaccine used in primary vaccination (first and second doses) contains a higher dose of mRNA (100 μg) as compared to the Comirnaty vaccine (30 μg) and has been associated with higher rates of adverse events, in particular at younger age. In line with this, we observed a higher risk of vaginal bleeding after Spikevax as compared to Comirnaty in premenopausal women. Also, a study analyzing the free-text fields of unsolicited reactions after COVID-19 vaccination in the CDC v-safe surveillance system found that a larger proportion of respondents with PMB had received the Spikevax vaccine than expected if vaccine type were independent.

(...) Our findings indicate that the COVID-19 vaccines, or the host response to them, can lead to vaginal bleeding in a wide range of women. Unexpected vaginal bleeding in post-, peri-, and premenopausal women generally have different underlying causes. However, our findings of an increased risk across the reproductive stages raise the possibility that the mechanisms linking COVID-19 vaccination to unexpected vaginal bleeding may be similar across the stages. Although our data are not fit to explore biological mechanisms, the increased risk after vaccination across different stages of reproductive aging (i.e., in post-, peri-, and premenopausal women) and exogenous hormone use may suggest that the mechanism is not through disruptions of the hypothalamic-pituitary-ovarian axis. Increased risk after both Comirnaty and Spikevax suggest a mechanism related to the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) spike protein and not to other vaccine components. This is also supported by a higher risk observed after Spikevax in premenopausal women. An increased risk of PMB diagnosis after SARS-CoV-2 infection has also been described, further supporting a role of the viral agent. Pathways related to local changes in the endometrium, possibly resulting from a spike related immune response or related to the endometrial expression of angiotensin-converting enzyme 2 (ACE2) receptors (i.e., the receptor for the SARS-CoV-2 spike protein) may be involved. However, a general bleeding tendency after vaccination cannot be ruled out.

(...) Together with current knowledge, it seems probable that both pre- and postmenopausal women are at increased risk of unexpected vaginal bleeding after COVID-19 vaccination. Our findings must be confirmed by well-designed prospective studies and such events should be addressed in clinical trials of future vaccines.

Organ and System-Specific Disorders

Immune-Mediated Hepatitis	Inflammation of the liver that results from an abnormal immune response. The body's immune system mistakenly attacks liver cells, leading to liver inflammation and damage. It can be caused by various factors, including autoimmune diseases or reactions to certain medications. Symptoms may include fatigue, jaundice, abdominal pain, and elevated liver enzymes.
Acute Kidney Injury	A sudden and often reversible decline in kidney function, characterized by a rapid decrease in the kidneys' ability to filter and eliminate waste products from the blood. Common causes include dehydration, severe infections, medications, and reduced blood flow to the kidneys. Symptoms may include decreased urine output, fluid retention, and electrolyte imbalances.
Nephrotic Syndrome	Kidney disorder characterized by the presence of excess protein in the urine, low levels of protein in the blood, and swelling (edema) in various parts of the body. It is often caused by damage to the glomeruli, the filtering units of the kidneys. Common underlying conditions include glomerulonephritis and certain systemic diseases. Symptoms may include edema, foamy urine, and elevated cholesterol levels.
Haematuria	Presence of blood in the urine. This condition can manifest visibly (gross hematuria) or be detectable only under a microscope (microscopic hematuria). Hematuria may result from a range of causes, including urinary tract infections, kidney stones, injury, inflammation, or more serious conditions like kidney disease or bladder cancer.
Additional organ- and system-specific disorders	A category encompassing various medical conditions that affect specific organs or systems in the body beyond those already addressed in this section. The inclusion of these disorders further illustrates the diverse range of health issues that can impact different organs and systems, contributing to a comprehensive understanding of the complexity of the risks attributed to these novel technologies.

AUTOIMMUNE HEPATITIS DEVELOPING AFTER CORONAVIRUS DISEASE 2019 (COVID-19) VACCINE: CAUSALITY OR CASUALTY?

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8056822/

Findings

(...) We have recently treated a 35-year-old Caucasian female in her third month postpartum, who developed autoimmune hepatitis after COVID-19 vaccination. During pregnancy, she was diagnosed with gestational hypertension and started on labetalol 100 mg bid. C-section was performed without any complications, and patient was discharged from the hospital on labetalol for blood pressure control. She resumed her job as a healthcare provider in mid-December, and received her first dose of Pfizer-BioNTech COVID-19 vaccine on January 4th. After 1 week, she started developing generalized pruritus, then choluria, and finally noticed jaundice, presenting to the emergency room on day +13 after COVID-19 vaccination. (…)

To our knowledge, this is the first reported episode of autoimmune hepatitis developing post-COVID-19 vaccination, raising concern regarding the possibility of vaccine-induced autoimmunity. As causality cannot be proven, it is possible that this association is just coincidental. However, severe cases of SARS-CoV-2 infection are characterized by an autoinflammatory dysregulation that contributes to tissue damage. As the viral spike protein appears to be responsible for this, it is plausible that spike-directed antibodies induced by vaccination may also trigger autoimmune conditions in predisposed individuals. In support of this, several cases of ITP have been reported days after COVID-19 vaccination. (…)

Several atypical features of her presentation deserve further discussion. First, immunoglobulin G levels were not elevated as typically reported for autoimmune hepatitis. However, Hartl et al. recently reported that ~10% of patients with autoimmune hepatitis had normal immunoglobulin G levels at presentation. Second, histology revealed the presence of eosinophils, which are more commonly seen with drug or toxin induced liver injury. However, they can be found in cases of autoimmune hepatitis. It is also possible that we could be in the presence of a vaccine-related drug-induced liver injury with features of autoimmune hepatitis, as previously described for nitrofurantoin or minocycline. In line with this, the patient has already started a prednisone taper, as patients with well documented drug-induced AIH do not typically show relapses after steroid discontinuation. Finally, symptoms developed 6 days after vaccination, which instinctively appears as a short period of time. However, latency periods after vaccination of just days have been observed in prior reports.

In summary, autoimmune hepatitis developed in a healthy 35-year-old female in her third month postpartum. Whether there exists a causal relationship between COVID-19 vaccination and the development of autoimmune hepatitis remains to be determined. We are hopeful that this manuscript will not discourage healthcare providers from getting and prescribing COVID-19 vaccines, but that it will raise awareness about potential side effects that will likely emerge as we continue to vaccinate more people. Only long-term follow-up of large cohorts of patients receiving the vaccine will answer the question as to whether it increases the risk of autoimmune conditions. Until then, healthcare providers are encouraged to remain vigilant.

IMMUNE-MEDIATED HEPATITIS WITH THE MODERNA VACCINE, NO LONGER A COINCIDENCE BUT CONFIRMED

SOURCE: https://www.sciencedirect.com/science/article/pii/S0168827821020936

Introduction

We have read with interest the recent cases suggesting the possibility of vaccine-induced immune-mediated hepatitis with Pfizer-BioNTech and Moderna mRNA-1273 vaccines for the SARS-CoV-2 virus. However, as the cohort of vaccinated individuals against COVID-19 increases, the previously reported cases could not exclude a coincidental development of autoimmune hepatitis, which has an incidence of 3/100,000 population per year. Our case demonstrates conclusive evidence of vaccine-induced immune-mediated hepatitis with a rapid onset of liver injury after the first Moderna dose, which on re-exposure led to acute severe autoimmune hepatitis.

Discussion

This case illustrates immune-mediated hepatitis secondary to the Moderna vaccine, which on inadvertent re-exposure led to worsening liver injury with deranged synthetic function. This occurred in a well man with no other medical problems. The onset of jaundice associated with the mRNA vaccine was unusually rapid. This was also illustrated in the other cases where symptoms developed over a median of 7 days (range 4-35). Latency is usually longer in other causes of DILI, but can vary depending on mode of injury.

The mRNA vaccine pathway triggers pro-inflammatory cytokines including interferon and cross-reactivity has been illustrated between the antibodies against the spike protein and self-antigens.9,10

Seven cases of suspected immune-mediated hepatitis have been reported with SARS-2-COV mRNA vaccines (3 with Pfizer and 4 with Moderna). Liver histology was assessed in every case and findings were similar to ours, indicating acute hepatitis with interface hepatitis, lymphoplasmacytic infiltrate and absence of fibrosis. Eosinophils as part of the infiltrate, which can be noted in DILI were present in 3 cases. All 7 patients responded well to steroids (n = 5 prednisolone, n = 1 budesonide and n = 1 methylprednisolone). In 3 cases there were features suggesting coincidental autoimmune hepatitis: a 35-year-old lady in her third trimester of pregnancy with positive double-stranded DNA, an 80-year-old lady with a history of autoimmune conditions and a 41-year-old lady with strongly positive auto-antibody panel after both doses of vaccination. In the other 4 cases, a raised IgG, with at least 1 positive antibody was noted in 3 cases.

This case has confirmed immune-mediated hepatitis secondary to the Moderna vaccine, which on inadvertent re-exposure led to acute severe hepatitis. Treatment with corticosteroid therapy appears to be favourable. We wish to highlight that immune-mediated reactions from the SARS-CoV-2 mRNA vaccines are very rare and during the COVID pandemic, the vaccination programme continues to be crucial. We report this case to encourage vigilance for drug-induced reactions and to raise awareness to vaccination centres to incorporate it into their routine checks before administering second doses. Long-term follow up of identified individuals will be essential in determining the prognosis of this immune-mediated liver injury.

ACUTE KIDNEY INJURY AFTER COVID-19 VACCINES: A REAL-WORLD STUDY

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9196826/

Abstract

Background

Acute kidney injury (AKI), a rare adverse event, cannot be ignored as millions of doses of coronavirus disease 2019 (COVID-19) vaccinations. We aimed to investigate the occurrence of post-vaccine AKI reported to the Vaccine Adverse Event Reporting System (VAERS).

Methods

After data mapping from December 2020 to June 2021, we summarized demographic and clinical features and outcomes of reported cases from three vaccines (Pfizer-BNT, MODERNA, and JANSSEN). The Bayesian and nonproportional analyses explored the correlations between COVID-19 vaccines and AKI.

Results

We identified 1133 AKI cases. Pfizer-BNT appeared to have a stronger AKI correlation than MODERNA and JANSSEN, based on the highest reporting odds ratio (ROR = 2.15, 95% confidence interval = 1.97, 2.36). We observed the differences in ages, comorbidities, current illnesses, post-vaccine AKI causes, and time to AKI onset (all $p < .05$) among three vaccines. Most patients are elderly, with the highest age in MODERNA (68.41 years) and lowest in JANSSEN (59.75 years). Comorbidities were noticed in 58.83% of the cases and active infections in over 20% of cases. The leading cause of post-vaccine AKI was volume depletion (40.78%), followed by sepsis (11.74%). Patients in Pfizer-BNT had the worst outcome with 19.78% deaths, following 17.78% in MODERNA and 12.36% in JANSSEN ($p = .217$). The proportion of patients on dialysis was higher in JANSSEN than in Pfizer-BNT and MODERNA (14.61% vs. 6.54%, 10.62%, $p = .008$).

Conclusion

AKI could occur after the COVID-19 vaccines, predominantly in elderly patients. However, the causality needs further identification.

NEW-ONSET NEPHROTIC SYNDROME AFTER JANSSEN COVID-19 VACCINATION: A CASE REPORT AND LITERATURE REVIEW

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8329389/

Abstract

Here, we report a 51-year-old healthy man with nephrotic syndrome secondary to minimal change disease (MCD) after Ad26.COV. (Janssen) vaccination. He had no comorbid disease and received Ad26.COV.2 on April 13, 2021. Seven days after vaccination, he developed edema and foamy urine. Edema rapidly aggravated with decreased urine volume. He was admitted to the hospital 28 days after vaccination, and his body weight increased by 21 kg after vaccination. (…) This case highlights the risk of new-onset nephrotic syndrome secondary to MCD after vectored COVID-19 vaccination. Although the pathogenesis is uncertain, clinicians need to be careful about adverse renal effects of COVID-19 vaccines.

Introduction

In this case report, we present a case of a patient who suffered full-blown nephrotic syndrome secondary to minimal change disease (MCD) after being administered the vectored COVID-19 vaccine, Ad26.COV.2 (Janssen).

Discussion

Foot process effacement of podocytes, visible by electron microscopy, are the hallmark of MCD. Although the exact pathogenesis is still unelucidated, podocyte injury by circulating factors released by T cells is considered the main mechanism. The increased proportion of circulating CD8+ T suppressor cells and type 2 T helper cells that secrete various cytokines, such as interleukin 4, 5, 9, 10, and 13, has been confirmed in studies. There are several cases of new-onset nephrotic syndrome by podocytopathies associated with COVID-19. The presence of angiotensin-converting enzyme 2, which helps SARS-CoV-2 invasion presents in podocytes, may be related to the podocytopathies. Also, the mechanism is unclear, but this case suggests that the adenovirus-based vectored vaccine for COVID-19 can affect T-cell function, and it can also occur rapidly within days after vaccination.

There are several cases of new-onset and relapsing MCD after COVID-19 vaccination and Table 1 summarizes these cases. All cases of MCD occurred within 10 days after vaccination with the first dose and the histopathological findings showed typical MCD findings. In addition, most cases of MCD were from mRNA vaccination, and our case is the first case of new-onset MCD after vectored vaccination. Fortunately, steroid treatment was effective in most cases except the patient who had underlying chronic kidney disease. Taken together, both vectored and mRNA COVID-19 vaccines can affect immune regulation, especially T cell-related, so there is a risk of new-onset and relapsing MCD.

Also, vaccination-related nephrotic syndrome secondary to MCD was reported in other vaccines, such as influenza, hepatitis B, pneumococcus, and measles.The pathogenic mechanism of podocyte foot process effacement after vaccination has been suggested that vaccination stimulates antigen-presenting and B cells. Stimulated antigen-presenting and B cells lead to antigen presentation and cytokine production, thereby activating T cells causing podocyte injury. Most MCD cases after vaccination occurred within two weeks after vaccination and many cases were accompanied by severe acute kidney injury. Therefore, clinicians need to be careful about the occurrence of proteinuria or edema after vaccination.

Here, we report the adverse effect of new-onset nephrotic syndrome secondary to MCD following Ad26.COV2.S. Clinicians need to be aware of the possibility of uncommon adverse effects after COVID-19 vaccination and prepare for proper management.

NEPHROTIC SYNDROME FOLLOWING CHADOX1 NCOV-19 VACCINE AGAINST SARSCOV-2

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8257404/

Findings

There have been multiple reports of nephrotic syndrome following the Pfizer-BioNTech coronavirus disease 2019 vaccine. We report a similar case of nephrotic syndrome which developed shortly after receiving ChAdOx1 nCoV-19 (Chimpanzee Adenovirus vectored Oxford university - novel CoronaVirus 2019 vaccine) vaccine against severe acute respiratory syndrome coronavirus 2 developed by Oxford University and AstraZeneca (Covishield, Serum Institute of India, Pune, India). It is a viral vector vaccine developed using the modified chimpanzee adenovirus ChAdOx1 as a vector.

A 19-year-old girl presented with generalized body swelling, which started 8 days after the first dose of the Covishield coronavirus disease 2019 vaccine. Clinical examination was unremarkable except for generalized edema. Blood tests revealed serum creatinine, 1.09 mg/dl; albumin, 2.15 g/dl; and total cholesterol, 274 mg/dl; and a urine protein creatinine ratio of 3.18 g/g. Additional evaluation for secondary causes was negative. Kidney biopsy results revealed 11 glomeruli with normal capillary walls with diffuse and global mesangial cell proliferation on light microscopy (Figure 1). The glomerular walls did not stain for immunoglobulins or complement, but there was mesangial trapping of immunoglobulin M (IgM[1+]) and C3(1+). A diagnosis of a mesangial proliferative variant of minimal change disease was made. She responded to oral prednisone 1 mg/kg body weight with clinical and biochemical remission.

To the best of our knowledge, this is a first ever report of nephrotic syndrome after the ChAdOx1 nCoV-19 vaccine. The temporal profile of nephrotic syndrome after the coronavirus disease 2019 vaccination and absence of any other precipitating factors points toward the vaccine as a possible trigger. It is uncertain if she should be advised to take the second dose and when it can be safely taken.

ACUTE KIDNEY INJURY WITH GROSS HEMATURIA AND IGA NEPHROPATHY AFTER COVID-19 VACCINATION

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8329426/

Findings

The mRNA coronavirus disease 2019 (COVID-19) vaccines induce an IgG response that prevents people from contracting severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Interestingly, there are now at least 6 cases of gross hematuria reported in patients with a history of biopsy-proven IgA nephropathy (IgAN), involving both mRNA vaccines. All of the previous patients were treated with supportive therapy with rapid resolution of hematuria and no acute kidney injury (AKI). It has been reported in preclinical trials that nasal shedding of SARS-CoV-2 still occurred after vaccination with both mRNA vaccines, suggesting a lack of a mucosal IgA response. We also cared for 2 patients who had prior biopsy-proven IgAN, who developed gross hematuria after their second dose of the Pfizer vaccine, without a preceding COVID-19 infection. Table 1 outlines the clinical data. Our first patient presented 5 days after his second dose, with nonspecific myalgias, chills, headache, dysuria, and gross hematuria within 24 hours of initial symptoms. Previous IgAN flares in this patient were precipitated by upper respiratory infections and were limited to gross hematuria with no AKIs and no requirement for steroids in the past. His postvaccine workup was notable for AKI, with a serum creatinine level of 3.53 mg/dl and a urine protein–creatinine ratio of 3.0. He was empirically started on steroids with recovery to baseline renal function at 1 month and recovery to baseline proteinuria within 2 months. Our second patient developed gross hematuria within 24 hours of receiving his second dose. His hematuria resolved after 3 days with supportive therapy only. To our knowledge, we are the first to report an IgAN flare that has led to an AKI that resolved with steroid therapy. We agree that it is not clear how a nonmucosal immune challenge led to an IgAN exacerbation; however, the delayed-type hypersensitivity reactions seen in our patients suggest a cell-mediated immune response, not an antibody response. We offer further evidence that patients with IgAN warrant close monitoring after receiving their second mRNA vaccine dose.

HAEMATURIA, A WIDESPREAD PETECHIAL RASH, AND HEADACHES FOLLOWING THE OXFORD ASTRAZENECA CHADOX1 NCOV-19 VACCINATION

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8499345/

Abstract

With increasing presentations of headaches following COVID-19 vaccination, we present one of the UK's earliest proven cases of vaccine-induced thrombotic thrombocytopaenia (VITT), with the aim of giving colleagues a case to compare other patients against. Our patient was a 48-year-old man who presented with frank haematuria, a widespread petechial rash, and headaches, 2 weeks after receiving the first dose of the Oxford AstraZeneca ChAdOx1 nCoV-19 vaccine. He had a platelet count of 14×109/L and an extensive cerebral venous sinus thrombosis (CVST) with subarachnoid haemorrhage on imaging. He developed localising neurological signs and experienced a cardiopulmonary arrest. He was successfully resuscitated and transferred to a tertiary care centre for urgent thrombectomy. This case illustrates how the diagnosis of VITT should be based on the platelet count and imaging—and how patients with VITT should be cared for in centres with urgent neurosurgical and interventional radiology services.

Discussion

VITT is a newly recognised phenomenon,1 with only a handful of cases being described in the literature. Patients described in these cases are often younger adults who have the diagnostic hallmark of a low platelet count and thrombosis following inoculation with the Oxford AstraZeneca ChAdOx1 nCoV-19 vaccine. Patients with VITT commonly present with headaches, and such patients often have a CVST that may also deteriorate into an intracranial haemorrhage. However, other rarer thromboses can also occur with VITT, such as deep vein thromboses in the abdomen, pulmonary emboli, or arterial thrombi that can cause ischaemia.

Our case was unique from other reported cases as our patient presented with frank haematuria and a widespread petechial rash, which has not been commonly described in the literature. It was also unique in revealing how rapidly clot can form —this was highlighted when clot was seen rapidly forming in the cerebral venous sinuses at the same time as established clot was being mechanically removed during thrombectomy.

As of June 2021, 389 cases of VITT were reported in the UK following vaccination with the Oxford AstraZeneca ChAdOx1 nCoV-19 vaccine, occurring almost equally in men and women. 31 of these reported cases were after the second dose of the vaccine. CVSTs have been reported in 140 of all VITT cases—at an average age of 46 years—while the remaining 249 cases have had other thromboses. (…) There have been 68 reported deaths from VITT in the UK thus far (case fatality rate of 17%), with 4 of these occurring after receipt of the second dose of the vaccine. (…)

The fact that patients have anti-PF4 IgG antibodies and a positive HIT ELISA assay after receiving a dose of the Oxford AstraZeneca ChAdOx1 nCoV-19 vaccine, and without any exposure to heparin, points to an autoimmune process linked to the vaccine. (…)

Although most discussion around VITT—including this case—involves the Oxford AstraZeneca ChAdOx1 nCoV-19 vaccine, other adenovirus vector vaccines have now also been shown to also have a small risk of inducing VITT.7 We would recommend that the Panel add these vaccines to the guidance as the COVID-19 vaccine programme continues and more data become available.

RISK ASSESSMENT OF RETINAL VASCULAR OCCLUSION AFTER COVID-19 VACCINATION

SOURCE: https://pubmed.ncbi.nlm.nih.gov/37130882/

Abstract

Coronavirus disease 2019 (COVID-19) vaccines are associated with several ocular manifestations. Emerging evidence has been reported; however, the causality between the two is debatable. We aimed to investigate the risk of retinal vascular occlusion after COVID-19 vaccination. This retrospective cohort study used the TriNetX global network and included individuals vaccinated with COVID-19 vaccines between January 2020 and December 2022. We excluded individuals with a history of retinal vascular occlusion or those who used any systemic medication that could potentially affect blood coagulation prior to vaccination. To compare the risk of retinal vascular occlusion, we employed multivariable-adjusted Cox proportional hazards models after performing a 1:1 propensity score matching between the vaccinated and unvaccinated cohorts. Individuals with COVID-19 vaccination had a higher risk of all forms of retinal vascular occlusion in 2 years after vaccination, with an overall hazard ratio of 2.19 (95% confidence interval 2.00-2.39). The cumulative incidence of retinal vascular occlusion was significantly higher in the vaccinated cohort compared to the unvaccinated cohort, 2 years and 12 weeks after vaccination. The risk of retinal vascular occlusion significantly increased during the first 2 weeks after vaccination and persisted for 12 weeks. Additionally, individuals with first and second dose of BNT162b2 and mRNA-1273 had significantly increased risk of retinal vascular occlusion 2 years following vaccination, while no disparity was detected between brand and dose of vaccines. This large multicenter study strengthens the findings of previous cases. Retinal vascular occlusion may not be a coincidental finding after COVID-19 vaccination.

Discussion

We demonstrated a higher risk and incidence rate of retinal vascular occlusion following COVID-19 vaccination, after adjusting for potential confounding factors. The risk of retinal vascular occlusion, except for CRAO, has been promptly observed in individuals receiving vaccines against SARS-CoV-2. The risk factors for retinal vascular occlusion include diabetes, hypertension, obesity, coronary artery disease, and stroke. To ensure the reliability of the results, we appropriately balanced the baseline characteristics in both cohorts before analysis.

The widespread occurrence of microvascular thrombosis in COVID-19 patients have been demonstrated. Vaccination with ChAdOx1 nCoV-19 can result in the rare development of immune thrombotic thrombocytopenia mediated by platelet-activating antibodies against platelet factor 4 (PF4), which clinically mimics autoimmune heparin-induced thrombocytopenia. A large cohort study showed that the risk of VTE slightly increased 1.10-fold 8–14 days after ChAdOx1 nCoV-19 vaccination but found no difference for individuals who were administered BNT162b2 vaccination; the risk of ATE following ChAdOx1 nCoV-19 and BNT162b2 vaccination increased 1.21-fold and 1.06-fold, respectively.

Miscellaneous Events

This chapter delves into several significant adverse events associated with COVID-19 vaccination, drawing from a series of detailed case studies and systematic reviews. These events range from vaccine-induced immune thrombotic thrombocytopenia (VITT) and myocarditis to death following administration of specific COVID-19 vaccines. This chapter synthesizes various clinical reports, autopsy findings, and reviews to highlight the pathophysiology, clinical presentation, and potential mechanisms underlying these adverse events. Through a comprehensive analysis of these cases, this section aims to provide a nuanced understanding of the severe complications associated with COVID-19 vaccines, emphasizing the need for vigilance and further research in vaccine safety monitoring.

VACCINE-INDUCED IMMUNE THROMBOTIC THROMBOCYTOPENIA WITH DISSEMINATED INTRAVASCULAR COAGULATION AND DEATH FOLLOWING THE CHADOX1 NCOV-19 VACCINE

SOURCE: https://www.strokejournal.org/article/S1052-3057(21)00341-4/fulltext

Abstract

We report a fatal case of vaccine-induced immune thrombotic thrombocytopenia (VITT) after receiving the first dose of the ChAdOx1 nCoV-19 vaccine. We attribute this fatal thrombotic condition to the vaccine due to the remarkable temporal relationship. The proposed mechanism of VITT is production of rogue antibodies against platelet factor-4 resulting in massive platelet aggregation. Healthcare providers should be aware of the possibility of such fatal complication, and the vaccine recipients should be warned about the symptoms of VITT.

Introduction

(...) Traditionally, vaccine development progresses through several pre-clinical and clinical stages occurring sequentially, and each may take a considerable time for completion. This was not the case with the COVID-19 vaccine as these stages were accelerated to an unprecedented pace with a seamless transition from one stage to the other over a few months. Inactivated or live-attenuated viruses as well as recombinant proteins and vectors technologies have been deployed to develop the COVID-19 vaccine. In addition, new platforms such as RNA and DNA vaccines are also used for the first time in a licensed vaccine. We report a fatal case of vaccine-induced immune thrombotic thrombocytopenia (VITT) after receiving the first dose of the ChAdOx1 nCoV-19 vaccine with emphasis on the possible pathophysiology behind this complication.

Discussion

(...) The ChAdOx1 nCoV-19 vaccine is a viral vector vaccine that uses modified chimpanzee adenovirus ChAdOx1 as a vector. The safety profile of the vaccine is acceptable with commonly reported mild side effects such as injection-site pain, nausea, and headache that resolve within a few days. The vaccine was linked to severe thrombotic events with the majority of the cases occurring in women under the age of 60 within 2 weeks of receiving the first dose. In addition, cerebral venous sinus thrombosis was found to usually occur with low levels of platelets (thrombocytopenia). The mechanism of thrombosis is that the viral proteins and free DNA in the vaccine bind to platelet factor 4 to generate a neoantigen that subsequently leads to the development of antibodies against platelet factor 4 which activate platelets and promote clotting. The phenomenon is similar to autoimmune heparin-induced thrombocytopenia (aHIT). Our case reflects this mechanism with fulminant consumptive coagulopathy and thrombocytopenia leading to extensive thrombosis co-occurring with bleeding diathesis.

The antibodies associated with the ChAdOx1 nCoV-19 vaccine can be detected by platelet factor 4/heparin enzyme-immunoassays, which are commercially available to diagnose HIT. However, this test was not performed for our patient. Recent articles reported successful treatment of VITT using intravenous immunoglobulin (IVIG), which prevents platelet activation by anti-platelet factor 4 antibodies. VITT is a rapidly fatal disorder if not recognized and treated early. A recent post-mortem study of VITT reported extensive involvement of large venous vessels with thrombotic occlusions in the microcirculation of multiple organs as well as increased inflammatory infiltrates. These findings indicated the progression of an inflammatory process that culminates in microvascular injury of multiple organs by iatrogenic activation of the innate immune system along with the complement pathway.

Conclusion

The report presents a rare occurance of a florid thrombotic thrombocytopenia after the first dose of the ChAdOx1 nCoV-19 vaccine. We attribute this fatal thrombotic condition to the vaccine due to the remarkable temporal relationship. The proposed mechanism of VITT is production of rogue antibodies against platelet factor-4 resulting in massive platelet aggregation. The case should alert healthcare providers to the possibility of such precipitously fatal complication while vaccine recipients should be warned about the symptoms of VITT.

MYOCARDITIS-INDUCED SUDDEN DEATH AFTER BNT162B2 MRNA COVID-19 VACCINATION IN KOREA: CASE REPORT FOCUSING ON HISTOPATHOLOGICAL FINDINGS

SOURCE: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8524235/

Abstract

We present autopsy findings of a 22-year-old man who developed chest pain 5 days after the first dose of the BNT162b2 mRNA vaccine and died 7 hours later. Histological examination of the heart revealed isolated atrial myocarditis, with neutrophil and histiocyte predominance. Immunohistochemical C4d staining revealed scattered single-cell necrosis of myocytes which was not accompanied by inflammatory infiltrates. Extensive contraction band necrosis was observed in the atria and ventricles. There was no evidence of microthrombosis or infection in the heart and other organs. The primary cause of death was determined to be myocarditis, causally-associated with the BNT162b2 vaccine.

Introduction

The coronavirus disease 2019 (COVID-19) pandemic, which started in January 2020 has affected people worldwide. Rapid vaccine development has enabled COVID-19 prevention. Two mRNA COVID-19 vaccines, BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna) demonstrated safety and efficacy in clinical trials, and were granted emergency use authorization by the US Food and Drug Administration in December 2020. As the number of people vaccinated against COVID-19 has increased, there have been multiple reports of myocarditis as an adverse event following immunization, which was not observed in clinical trials.

Myocarditis is histologically characterized by diffuse and/or focal inflammatory infiltrates within myocardial tissue, accompanied by myocyte damage without evidence of ischemia. Little is known about the histopathological characteristics of myocarditis following COVID-19 vaccination because endomyocardial biopsy is not a routine procedure for myocarditis and, due to its generally favorable prognosis, opportunities for autopsy studies are rare.

We recently observed a case of sudden cardiac death in a young male six days after receiving the first dose of the BNT162b2 mRNA vaccine and report the distinctive clinical and pathological findings of this case.

Discussion

There were three main histological findings in the heart: 1) myocarditis predominantly involving the atrial wall, with neutrophil and histiocyte predominance; 2) non-inflammatory single-cell necrosis; and 3) diffuse CBN throughout the myocardium, predominantly in the left ventricle. These pathological findings were not evident on macroscopic examination. The only abnormal gross finding was cardiac enlargement, which may have been secondary to hypertension.

In this case, the myocarditis was histologically different from viral or immune-mediated myocarditis in that the inflammatory infiltrates were predominantly neutrophils and histiocytes, rather than lymphocytes. (…) Thus, myocardial injury due to COVID-19 vaccination may histologically present not only as myocarditis, but also as scattered single-cell necrosis, similar to myocardial lesions of COVID-19. (…)

Vaccine-associated myocarditis has been reported predominantly in young males after the second vaccination. (…) This unique case provides an example of a serious adverse event following COVID-19 mRNA vaccination. It is unknown whether this case is related to the vaccine type or to a specific vaccine component. It is also unclear whether the location (atrium), type of inflammation (neutrophils and histiocytes), CBN, and single-cell necrosis without inflammation are specific characteristics of COVID-19 vaccine-associated myocarditis. Comprehensive clinical and pathological evaluation of additional cases is needed to clarify the relationship between COVID-19 vaccination and myocarditis.

POST-MORTEM FINDINGS IN VACCINE-INDUCED THROMBOTIC THOMBOCYTOPENIA

SOURCE: https://haematologica.org/article/view/haematol.2021.279075

Introduction

Greinacher et al. and Schultz et al. were the first to independently report the main clinical and laboratory features of 11 and five respective patients from Germany, Austria and Norway who developed life-threatening thrombohemorrhagic complications 5 to 16 days after the administration of the first dose of the chimpanzee adenoviral vector vaccine ChAdOx1nCoV-19 against SARS-CoV-2 and COVID-19. Subsequently Scully et al. reported similar findings in 23 patients treated with the same vaccine in the United Kingdom. More recently, See et al. reported a case series of 12 patients from the USA with cerebral venous sinus thrombosis following the vaccination with Ad26.CoV2.S employing a human adenoviral vector. The main post-vaccination features common to the case series were the occurrence of venous thromboembolism mainly in unusual sites (cerebral and abdominal veins) and the concomitant presence of bleeding symptoms associated with severe thrombocytopenia, often accompanied by laboratory signs of consumption coagulopathy with low plasma fibrinogen and hugely increased levels of D-dimer. The majority of reported patients reacted positively for serum immunoglobulin G (IgG) antibodies to the platelet factor 4 PF4/heparin complex. Another common feature was the high mortality rate. The mechanism of this very rare thrombohemorrhagic syndrome was postulated to be a vaccine-triggered autoimmune reaction, with the development of antibodies against a still ill-defined PF4/polyanion complex that causes platelet activation as in heparin-induced thrombocytopenia (HIT), notwithstanding the fact that no cases were exposed to heparin before the onset of thrombosis and thrombocytopenia. We report herewith the detailed post-mortem macroscopic and microscopic findings in two similar cases that occurred in the Italian region of Sicily.

Discussion

From a clinical and laboratory standpoint these two fatal cases of venous thrombosis located in unusual sites are similar to those recently described, because in both cases complications occurred on average 10-15 days after vaccination and were accompanied by a very low platelet count, very high D-dimer and low fibrinogen with signs of consumption coagulopathy. Both patients had detectable anti PF-4/polyanion antibodies unrelated to the use of heparin and positive results were confirmed by reactivity inhibition in the presence of excess heparin in vitro. Patients tested negative for SARS-Cov-2 molecular assays and antibodies to the nucleocapsid and spike proteins, thus ruling out recent exposure to SARS-CoV-2 (Table 1). There was neither clinical and laboratory evidence of inherited or acquired thrombophilia nor of intake of prothrombotic medicines. Venous thrombosis was accompanied by severe intracranial bleeding, which was the final cause of death in both and developed after the administration of therapeutic doses of heparin in patient 1 but concomitantly with cerebral vein thrombosis and no anticoagulant in patient 2.

The peculiar features of these cases were the availability of macroscopic and microscopic autopsy findings. The main macroscopic finding was that venous thrombosis was much more widespread and catastrophic than diagnosed by imaging during life. (…)

All in all, this post-mortem examination of two typical cases of the novel vaccine-induced thrombotic thrombocytopenic syndrome (VITT) shows that the involvement of large venous vessels was much more extensive than appreciated by imaging during the brief clinical course of these fatal cases. Microscopic findings showed vascular thrombotic occlusions occurring in the microcirculation of multiple organs and increased inflammatory infiltrates. Immunohistochemical analyses highlighted the vascular and peri-vascular expression of adhesion molecules such as VICAM1, as well as the presence of CD66b+, CD163+ and CD61+ activated inflammatory cells, also expressing C1r. These findings indicate that the activation of the innate immune system and complement pathway promote the inflammatory process leading to the microvascular damage of multiple organs.

A SYSTEMATIC REVIEW OF AUTOPSY FINDINGS IN DEATHS AFTER COVID-19 VACCINATION

SOURCE: https://web.archive.org/web/20230706021406/https://papers.ssrn.com/sol3/papers.cfm?Abstract_id=4496137

SOURCE: Full Study (PDF)

Abstract

The rapid development and widespread deployment of COVID-19 vaccines, combined with a high number of adverse event reports, have led to concerns over possible mechanisms of injury including systemic lipid nanoparticle (LNP) and mRNA distribution, spike protein-associated tissue damage, thrombogenicity, immune system dysfunction, and carcinogenicity. The aim of this systematic review is to investigate possible causal links between COVID-19 vaccine administration and death using autopsies and post-mortem analysis.

Findings

The most implicated organ system in COVID-19 vaccine-associated death was the cardiovascular system (53%), followed by the hematological system (17%), the respiratory system (8%), and multiple organ systems (7%). Three or more organ systems were affected in 21 cases. The mean time from vaccination to death was 14.3 days. Most deaths occurred within a week from last vaccine administration. A total of 240 deaths (73.9%) were independently adjudicated as directly due to or significantly contributed to by COVID-19 vaccination.

Discussion

In summary, we identified a large series of deaths after COVID-19 vaccination, confirmed with autopsy and necropsy, to help the medical community better understand fatal COVID-19 vaccine syndromes. The consistency seen among cases in this review with known COVID-19 vaccine adverse events, their mechanisms, and related excess death, coupled with autopsy confirmation and physician-led death adjudication, suggests there is a high likelihood of a causal link between COVID-19 vaccines and death in most cases. Further urgent investigation is required for the purpose of clarifying our findings. Even with substantial evidence, our paper cannot definitively determine causality as our paper has all the limitations of systematic reviews of previously published papers including selection bias, publication bias, and confounding variables. Further urgent investigation is required aimed at confirming our results and further elucidating the mechanisms underlying the described fatal outcomes with the goal of risk mitigation for the large numbers of individuals who have taken one or more COVID-19 vaccines.

AUTOPSY FINDINGS AND CAUSALITY RELATIONSHIP BETWEEN DEATH AND COVID-19 VACCINATION: A SYSTEMATIC REVIEW

SOURCE: https://pubmed.ncbi.nlm.nih.gov/34945172/

Abstract

The current challenge worldwide is the administration of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine. Considering that the COVID-19 vaccination represents the best possibility to resolve this pandemic, this systematic review aims to clarify the major aspects of fatal adverse effects related to COVID-19 vaccines, with the goal of advancing our knowledge, supporting decisions, or suggesting changes in policies at local, regional, and global levels. Moreover, this review aims to provide key recommendations to improve awareness of vaccine safety. All studies published up to 2 December 2021 were searched using the following keywords: “COVID-19 Vaccine”, “SARS-CoV-2 Vaccine”, “COVID-19 Vaccination”, “SARS-CoV-2 Vaccination”, and “Autopsy” or “Post-mortem”. We included 17 papers published with fatal cases with post-mortem investigations. A total of 38 cases were analyzed: 22 cases were related to ChAdOx1 nCoV-19 administration, 10 cases to BNT162b2, 4 cases to mRNA-1273, and 2 cases to Ad26.COV2.S. Based on these data, autopsy is very useful to define the main characteristics of the so-called vaccine-induced immune thrombotic thrombocytopenia (VITT) after ChAdOx1 nCoV-19 vaccination: recurrent findings were intracranial hemorrhage and diffused microthrombi located in multiple areas. Moreover, it is fundamental to provide evidence about myocarditis related to the BNT162B2 vaccine. Finally, based on the discussed data, we suggest several key recommendations to improve awareness of vaccine safety.

Discussion

Based on the discussed data, a causality relationship between vaccine administration and death was demonstrated in 13 cases of ChAdOx1 nCOV-19 (AstraZeneca) vaccination, while it was excluded in the other 6 cases; in two cases the relationship was classified as “very likely”, and in the last one as “unlikely”. As concerns BNT162B2, of the ten cases reported in the literature, the causality relationship was established in one case, while in another case it was defined as “possible”. Finally, the causality relationship was established in one case of mRNA-1273 vaccination and classified as “possible” in the two cases related to the Ad26.COV2.S (Janssen) vaccine. As recently noted in a review published by Sharifian-Dorche et al. [36], other severe adverse effects have been described related to other authorized vaccines.

SERIOUS HARMS OF THE COVID-19 VACCINES: A SYSTEMATIC REVIEW

SOURCE: https://www.medrxiv.org/content/10.1101/2022.12.06.22283145v2.full.pdf

Abstract

BACKGROUND: Serious and severe harms of the COVID-19 vaccines have been downplayed or deliberately excluded by the study sponsors in high impact medical journals.

METHODS: Systematic review of papers with data on serious adverse events (SAEs) associated with a COVID-19 vaccine.

RESULTS: We included 18 systematic reviews, 14 randomised trials, and 34 other studies with a control group. Most studies were of poor quality. A systematic review of regulatory data on the two pivotal trials of the mRNA vaccines found significantly more SAEs of special interest with the vaccines compared to placebo, and the excess risk was considerably larger
than the benefit, the risk of hospitalisation. The adenovirus vector vaccines increased the risk of venous thrombosis and thrombocytopenia, and the mRNA-based vaccines increased the risk of myocarditis, with a mortality of about 1-2 per 200 cases. We found evidence of serious neurological harms, including Bell's palsy, Guillain-Barré syndrome, myasthenic disorder and stroke, which are likely due to an autoimmune reaction. Severe harms, i.e. those that prevent daily activities, were underreported in the randomised trials. These harms were very common in studies of booster doses after a full vaccination and in a study of vaccination of previously infected people.

CONCLUSIONS: Further randomised trials are needed. Authorities have recommended populationwide COVID-19 vaccination and booster doses. They do not consider that the balance between benefits and harms becomes negative in low-risk groups such as children and people who have already recovered from COVID-19 infection.

SERIOUS ADVERSE EVENTS OF SPECIAL INTEREST FOLLOWING MRNA COVID-19 VACCINATION IN RANDOMIZED TRIALS IN ADULTS

SOURCE: https://pubmed.ncbi.nlm.nih.gov/36055877/

Abstract

Introduction: In 2020, prior to COVID-19 vaccine rollout, the Brighton Collaboration created a priority list, endorsed by the World Health Organization, of potential adverse events relevant to COVID-19 vaccines. We adapted the Brighton Collaboration list to evaluate serious adverse events of special interest observed in mRNA COVID-19 vaccine trials.

Methods: Secondary analysis of serious adverse events reported in the placebo-controlled, phase III randomized clinical trials of Pfizer and Moderna mRNA COVID-19 vaccines in adults (NCT04368728 and NCT04470427), focusing analysis on Brighton Collaboration adverse events of special interest.

Results: Pfizer and Moderna mRNA COVID-19 vaccines were associated with an excess risk of serious adverse events of special interest of 10.1 and 15.1 per 10,000 vaccinated over placebo baselines of 17.6 and 42.2 (95 % CI -0.4 to 20.6 and -3.6 to 33.8), respectively. Combined, the mRNA vaccines were associated with an excess risk of serious adverse events of special interest of 12.5 per 10,000 vaccinated (95 % CI 2.1 to 22.9); risk ratio 1.43 (95 % CI 1.07 to 1.92). The Pfizer trial exhibited a 36 % higher risk of serious adverse events in the vaccine group; risk difference 18.0 per 10,000 vaccinated (95 % CI 1.2 to 34.9); risk ratio 1.36 (95 % CI 1.02 to 1.83). The Moderna trial exhibited a 6 % higher risk of serious adverse events in the vaccine group: risk difference 7.1 per 10,000 (95 % CI -23.2 to 37.4); risk ratio 1.06 (95 % CI 0.84 to 1.33). Combined, there was a 16 % higher risk of serious adverse events in mRNA vaccine recipients: risk difference 13.2 (95 % CI -3.2 to 29.6); risk ratio 1.16 (95 % CI 0.97 to 1.39).

Discussion: The excess risk of serious adverse events found in our study points to the need for formal harm-benefit analyses, particularly those that are stratified according to risk of serious COVID-19 outcomes. These analyses will require public release of participant level datasets.

ADVERSE EFFECTS OF COVID-19 VACCINES AND MEASURES TO PREVENT THEM

SOURCE: https://pubmed.ncbi.nlm.nih.gov/35659687/

Abstract

Recently, The Lancet published a study on the effectiveness of COVID-19 vaccines and the waning of immunity with time. The study showed that immune function among vaccinated individuals 8 months after the administration of two doses of COVID-19 vaccine was lower than that among the unvaccinated individuals. According to European Medicines Agency recommendations, frequent COVID-19 booster shots could adversely affect the immune response and may not be feasible. The decrease in immunity can be caused by several factors such as N1-methylpseudouridine, the spike protein, lipid nanoparticles, antibody-dependent enhancement, and the original antigenic stimulus. These clinical alterations may explain the association reported between COVID-19 vaccination and shingles. As a safety measure, further booster vaccinations should be discontinued. In addition, the date of vaccination should be recorded in the medical record of patients. Several practical measures to prevent a decrease in immunity have been reported. These include limiting the use of non-steroidal anti-inflammatory drugs, including acetaminophen to maintain deep body temperature, appropriate use of antibiotics, smoking cessation, stress control, and limiting the use of lipid emulsions, including propofol, which may cause perioperative immunosuppression. In conclusion, COVID-19 vaccination is a major risk factor for infections in critically ill patients.

Relevant Topics

This section serves as an expansive repository, encompassing a diverse array of subjects entwined within the realm of the COVID-19 pandemic. These investigations range from futuristic scenarios eerily resembling the unfolding events, to in-depth overviews offering a panoramic perspective of the pandemic's landscape.

Among these varied topics, notable investigations delve into alarming phenomena such as "Turbo" Cancers and Congealed Clots in Veins and Arteries, both linked to COVID-19 vaccination campaigns. Additionally, the discourse extends to the revelation of "Special batches" of vaccines, with varying risk levels, sparking significant ethical concerns.

The exploration also uncovers the disconcerting prospect of DNA Contamination arising from the administration of COVID-19 vaccines, raising substantial questions about unforeseen consequences. Additionally, the analysis scrutinizes the fallacious narrative surrounding mask efficacy, revealing the overlooked side-effects of consistent mask usage amid historically inaccurate claims of their efficacy in preventing the spread of the pandemic.

Furthermore, the chapter probes into the unsettling reality of Excess Deaths linked to COVID-19 vaccination campaign, adding to the mosaic of concerns surrounding these immunization drives.

This compilation of "Relevant Topics" stands as a multifaceted exploration, unraveling intricate facets of the pandemic landscape while shedding light on critical issues that challenge conventional narratives and demand a more comprehensive understanding and discourse.

Spars Pandemic 2025-2028:
A Futuristic Scenario for Public Health Risk Communications

Published in 2017, the “SPARS Pandemic 2025-2028" is a hypothetical scenario created by the Johns Hopkins Center for Health Security. It presents a hypothetical scenario to illustrate the public health risk communication challenges that could potentially emerge during a naturally occurring infectious disease outbreak requiring the development and distribution of novel or investigational drugs, vaccines, therapeutics, or other medical countermeasures. The scenario is set in the future in the years 2025-2028, in a world that is both more connected and more divided. It follows the outbreak of a novel coronavirus called St. Paul Acute Respiratory Syndrome Coronavirus (SPARS) and its impact on society. The scenario addresses issues such as information access, social fragmentation, communication strategies, and public response. The narrative unfolds through a series of chapters, each highlighting different aspects of the outbreak and its aftermath. Overall, the scenario aims to prompt discussion and consideration of effective risk communication strategies in future public health emergencies.

The following statement can be found on the Johns Hopkins website:

> “ ***Statement on Johns Hopkins Center for Health Security SPARS Pandemic 2025-2028: A Futuristic Scenario for Public Health Risk Communicators***
>
> *December 16, 2021 - A multidisciplinary team from the Johns Hopkins Center for Health Security developed, from 2015-17, a fictional narrative scenario, ‘The SPARS Pandemic 2025-2028: A Futuristic Scenario for Public Health Risk Communicators’, to illustrate the communication challenges that could erupt around the development and distribution of novel and/or investigational drugs, vaccines, and other therapeutics in a future public health emergency.*
>
> *The scenario is not a prediction: It is a teaching and training resource for public health officials, to help users envision problems that could plausibly emerge in the future, so that they can practice responses and better protect the public’s health. Any resemblances between the fictional scenario storyline and the COVID-19 pandemic are coincidental. The scenario was developed by experts in the clinical, epidemiological, sociocultural, and communication aspects of epidemic management, to assure the narrative’s scientific plausibility.* ”

When comparing the Johns Hopkins hypothetical study from 2017 with the real-world COVID pandemic scenario that developed afterwards, several parallels emerge. These include, though not exclusively:

- **Virus Origin:** Both scenarios involved the emergence of a novel coronavirus causing a global pandemic, leading to substantial health impacts and societal disruption.
- **Health System Response:** The SPARS scenario and the COVID-19 pandemic highlighted challenges in health system responses, including shortages of medical supplies, overwhelmed healthcare facilities, and the need for rapid vaccine development.
- **Societal Impact:** Both scenarios highlighted the societal impacts, such as disruptions in daily life, economic challenges due to lockdowns, and changes in public behavior, including mask-wearing and social distancing.
- **Public Health Communication:** The SPARS scenario emphasized the importance of effective risk communication strategies, echoing some of the challenges faced during the COVID-19 pandemic, such as disseminating accurate information, managing misinformation, and fostering public trust.

Spars Pandemic 2025-2028: A Futuristic Scenario for Public Health Risk Communications

SOURCE: https://centerforhealthsecurity.org/sites/default/files/2022-12/spars-pandemic-scenario.pdf

ARCHIVED: https://archive.org/details/spars-pandemic-scenario_202104

Key Points

- The research paper focuses on a hypothetical scenario of the SPARS pandemic from 2025 to 2028, illustrating the challenges in public health risk communication during an infectious disease outbreak.
- The narrative content of the scenario includes discussions on information dissemination, the impact of social media, government responses, medical countermeasure development, and public response, highlighting the importance of clear and cohesive messaging across traditional and social media platforms.
- The paper outlines lessons learned and challenges faced in public health communication, emphasizing the critical role of effective communication, consistent messaging, and flexible strategies in addressing public health emergencies and enhancing public understanding of disease outbreaks and vaccination efforts.

Narrative Content: The narrative encompasses various chapters, each addressing different aspects of the pandemic, including the outbreak, potential cures and vaccines, concerns about information dissemination, the impact of social media, government responses, medical countermeasure development, and public response. It also discusses the challenges posed by incomplete health information, communication dilemmas, and concerns about vaccine safety and efficacy. The paper highlights the importance of clear and cohesive messaging across traditional and social media platforms, and the necessity for effective outreach to specific populations such as ethnic and regional communities with diverse concerns.

Addressing Communication Challenges: The scenario also addresses the use of electronic health records for vaccine distribution, the need for flexible communication strategies when electronic media are unreliable, and the emergence of anti-vaccination movements across different communities. It demonstrates the complexities of managing public health communication in the face of evolving public sentiment, misinformed groups, and the limitations of electronic media during crises.

Importance of Clear and Cohesive Messaging: Ultimately, the paper underscores the critical role of effective communication, consistent messaging, and flexible strategies in overcoming challenges in public health risk communication during a pandemic. The paper details the challenges and successes in communicating public health information throughout the pandemic. Key events include the emergence of SPARS, the development of the Corovax vaccine, resistance to vaccination from various groups, concerns about side effects, and the end of the pandemic.

Lessons Learned and Challenges Outlined: The paper outlines a series of lessons learned and challenges faced in public health communication. These include issues such as maintaining public trust, responding to conflicting messages, tailoring messages for specific communities, addressing concerns about vaccine safety and efficacy, and effectively utilizing communication platforms.

Highlighting the Importance of Effective Communication: The summary highlights the importance of effective communication in addressing public health emergencies and enhancing public understanding of disease outbreaks and vaccination efforts. It also underscores the need for compassionate and transparent communication to address public concerns and facilitate effective responses to health crises.

Valuable Insights and Lessons Learned: Overall, the paper provides valuable insights into the complexities of public health communication during a pandemic and offers important lessons for future disease outbreaks and vaccination campaigns.

Overviews

The following presents a comprehensive exploration of the COVID-19 worldwide scenario from multifaceted perspectives. It offers an exploration of overlapping implications that challenge conventional narratives, questioning the certainty of predictions and critiquing media influence to emphasizing natural immunity and ethical concerns in vaccine administration. Through debates on regulatory transparency, political motives, vaccine contaminants, and immune stimulation, "Overviews" navigates the complex landscape of of this issue with depth and breadth, empowering you to engage critically and approach future challenges with pragmatism and informed insight.

‘Disease X’: Dr. Satvinder Singh and Dr. Shankara Chetty on Immunology, Gene Therapy, Media Influence, and Ethical Accountability WATCH VIDEO

The discussion questioned the certainty of predictions, suggesting potential agendas. Media manipulation and its influence on public opinion during a pandemic were criticized, along with shifting vaccine efficacy goalposts. Emphasis was placed on natural immunity and skepticism about mRNA technology in vaccines. Ethical concerns were raised about vaccine administration and informed consent challenges. Regulatory bodies' roles and transparency were questioned, particularly in vaccine contracts. Political motives in vaccine production, release of court-ordered documents, and concerns about vaccine contaminants were discussed. The importance of continuous immune stimulation, avoiding fear-mongering, and maintaining a pragmatic approach to future challenges was underscored.

Disease X Predictions and Pre-planned Outbreaks: The discussion raised concerns about the concept of Disease X, questioning the certainty in predicting an outbreak's timing and severity. Doctors pointed out the unpredictability of viruses and their emergence, suggesting that if such predictions are made with certainty, there might be an agenda behind it. They highlighted the inherent human ability to combat infections, emphasizing the historical evolution of the human immune system against a multitude of pathogens over thousands of years.

Media Influence and Vaccine Narrative: The doctors offer criticism regarding media manipulation and its role in shaping public perception, alerting to its influence on public opinion during a pandemic and the potential manipulation of information for specific agendas. They also questioned the constantly shifting goalposts of vaccine efficacy, from stopping infections to preventing severe illness and death. They highlighted concerns about misinformation, altering definitions (e.g., vaccine, gain-of-function), and the coercive nature of media-driven fear tactics influencing public decisions.

Immune System and Vaccine Technology: The doctors stressed the importance of natural immunity and adaptation to environmental factors for overall health. They highlighted the human body's innate ability to fight diseases and urged people to focus on strengthening their immune systems through natural means. The conversation emphasized the importance of natural immunity acquired through exposure. They also question the necessity of mRNA technology in vaccines, arguing that conventional protein-based vaccines could induce a similar immune response without the complexities associated with mRNA vaccines.

Vaccine Administration and Informed Consent: The doctors raised ethical concerns about vaccine administration, citing instances where proper storage requirements were not followed, potentially affecting efficacy. They highlighted the challenges of informed consent, particularly for illiterate populations, and the absence of complete information provided to individuals receiving vaccines.

Regulatory Competence and Transparency: The speakers question regulators' roles, highlighting data collection and warning dissemination rather than setting medical guidelines. They argue against mRNA vaccines, suggesting they may not stimulate the immune system like conventional vaccines. The discussion touched upon regulatory bodies' responsibilities, questioning their competence in adapting to technological advancements and ensuring transparency in vaccine contracts. Concerns were raised about the release of vaccine contracts under court orders, revealing potential irregularities and hidden agendas in the vaccine distribution process.

Government Actions, Vaccine Contaminants, and Accountability: Discussion touches on political motives influencing vaccine production and the release of documents under court orders, hinting at irregularities. Concerns arise regarding contaminants in vaccines—DNA fragments, heavy metals—allegedly leading to health risks, neurological conditions, and genetic changes. The doctors criticized the lack of clarity on responsible parties in case of adverse reactions and the risks associated with combining vaccines without understanding potential consequences.

Immune Stimulation, Fear-Mongering, and Preparedness: The importance of continuous immune stimulation and avoiding fear-mongering is highlighted. Encouragement to develop natural immunity, build relationships with healthcare professionals, and maintain a pragmatic approach to future challenges.

“Turbo” Cancers

The term "turbo cancer" has emerged as a subject of concern within discussions surrounding COVID-19 vaccination. Observations suggest a potential link between vaccination and the acceleration of cancer development, characterized by unusually aggressive tumor growth in young individuals and changes in tumor characteristics such as rapid growth, increased aggressiveness, and multifocality. These observations raise questions about the long-term effects and safety of COVID-19 vaccines on cancer development. Furthermore, challenges in accurate diagnosis, underreporting of adverse events, and potential connections to viral spike proteins deepen the complexity of the issue. The unresolved challenges underscore the need for further investigation and vigilance in monitoring the relationship between vaccination and cancer development, highlighting the importance of transparent reporting and informed discourse on this emerging phenomenon.

Rise in Aggressive 'Turbo Cancers'— Especially Among Younger People

WATCH VIDEO

Dr. Harvey Risch discussed the potential link between COVID-19 vaccines and the emergence of what he termed "turbo cancers." He highlighted that the development of cancer is a long-term process that might take years before becoming symptomatic. Dr. Risch pointed out unusual cases of aggressive cancers in young individuals, such as colon and breast cancer, that typically wouldn't occur at their ages or progress so rapidly. He suggested that the vaccines might impair the immune system's ability to recognize and combat abnormal cells, potentially allowing them to multiply unchecked. However, he acknowledged the challenge of definitively connecting vaccine administration to cancer diagnoses due to the lack of robust data linking vaccination status and subsequent cancer occurrences. He emphasized the importance of being vigilant about any unexplained bodily changes and advised seeking medical attention in such cases. Additionally, he addressed the possibility that reduced surveillance during the pandemic might have led to delays in cancer diagnoses but didn't attribute the "turbo-cancer" phenomenon to this factor.

Dr. Ute Krüger - COVID-19 Vaccination: Observations of a Pathologist (2nd Medical Symposium)

WATCH VIDEO
READ TRANSCRIPT

Mortality Rates Comparison: Dr. Krüger initially emphasizes the relatively low mortality rate associated with COVID-19, which she compares to other diseases like sarcoidosis. She raises concerns about the media's representation of this data.

Shift in Breast Cancer Characteristics: Dr. Krüger notes that, for the past 18 years, she specialized in breast cancer research and, since the fall of 2021, she observed significant changes in breast cancer cases. She points out that patients presented with more aggressive tumors, rapid tumor growth, and larger tumor sizes, with some tumors reaching sizes not previously observed.

Increased Aggressiveness: Using histological images and explanations, she provides examples of highly proliferative and aggressive breast tumors, expressing that such rapidly growing tumors appear to be on the rise. This increased aggressiveness was evident in higher proliferative activities, mitotic figures, and pathological features.

Multifocality: Dr. Krüger discussed multifocal tumor growth and bilateral involvement in breast cancer cases, suggesting that multiple tumor foci within the breast are more common now than in the past.

Recurrences: She pointed out that some patients, who had previously experienced breast cancer, were returning with recurrences shortly after receiving the COVID-19 vaccination, which she referred to as "exclusive tumor growth." These recurrences led to significant increases in tumor size within a few months.

Coincident Tumors: Dr. Krüger presents cases where patients had multiple primary tumors in different organs, a phenomenon she found unusual. She describes that these cases made tumor conferences more complex and challenging.

Benign Tumors: She mentions observing an increase in benign tumors, such as fibroadenomas, and notes that some of these tumors exhibit unusual proliferative domains, unlike what she had seen in the past.

Inflammatory Processes: Dr. Krüger points out inflammatory processes in breast tissue and highlights how she observes inflammation both in tumors and the surrounding breast tissue, suggesting a possible correlation with the COVID-19 vaccination.

Tumor Characteristics Shift: She indicates that tumors changed over time and that they are more aggressive and proliferative, with a higher likelihood of multifocality, recurrences, and coincident tumors.

Autopsies and Incorrect Information: Dr. Krüger highlights issues with conducting autopsies, emphasizing a lack of interest in performing them and the provision of incorrect information by clinicians. She discusses the challenges of obtaining accurate data, given that some clinical forms did not accurately reflect the COVID-19 vaccination status.

Increase in Aggressive Breast Cancer Cases: Dr. Ute Krüger notes a significant increase in the number of breast cancer cases with characteristics indicating aggressive growth, such as larger tumor sizes, more extensive involvement, and higher malignancy grades. The rise in younger patients with breast cancer is also highlighted.

Rapid Tumor Growth Post-Vaccination: Dr. Ute Krüger presents cases of individuals who had previously been cancer-free but experienced rapid tumor growth and metastases shortly after receiving a COVID-19 vaccine. These cases suggest a possible link between vaccination and accelerated cancer development.

Multiple Simultaneous Cancers: Unusually, patients are being diagnosed with multiple cancers in different organs simultaneously, a scenario that is typically rare. Dr. Ute Krüger emphasizes the rarity and concerns about such cases.

Pathologist's Challenges: The presentation discusses several challenges faced by pathologists, including discrepancies in information provided by clinics, the lack of microscopic assessments (histology) in some cases, and a lack of knowledge concerning the evaluation of microscopic findings. These challenges can hinder accurate diagnoses and investigations into potential vaccine-related health issues.

Inflammatory Conditions and Vasculitis: The presentation raises concerns about inflammatory conditions, such as myocarditis, and vasculitis in various organs following COVID-19 vaccination. These conditions might be indicative of adverse effects of vaccination.

Lack of Reporting to Medical Products Agencies: Dr. Ute Krüger highlights that very few physicians report suspected cases to medical products agencies, potentially leading to underreporting of adverse events.

Possible Connection to SARS-CoV-2 Spike Protein: Dr. Ute Krüger in the presentation discusses a potential link between the spike protein of the SARS-CoV-2 virus and various health issues, particularly concerning COVID-19 vaccines. Dr. Ute Krüger highlights research conducted in Sweden, where in vitro experiments indicate that the SARS-CoV-2 spike protein may impact DNA repair mechanisms. This raises concerns about the effects of the spike protein in a living organism (in vivo).

Three Illustrative Cases of Health Issues Post-COVID-19 Vaccination: Dr. Ute Krüger describes specific cases that are suspected to be linked directly to COVID-19 vaccines. These cases involve patients who developed rapidly growing tumors or experienced severe side effects shortly after vaccination. According to Dr. Ute Krüger, these include tumor growth, bleeding in the spinal cord, vasculitis, myocarditis, and thrombus formation, and suggests a connection with COVID-19 vaccines.

Unresolved Issues and Challenges: Dr. Ute Krüger expresses frustration over the lack of attention and response to their findings, including a meeting with the Medical Products Agency being canceled after initially being scheduled.

Congealed Clots in Veins and Arteries

Congealed clots in veins and arteries refer to abnormal formations within the bloodstream that exhibit distinct characteristics differing from typical clots. These clots have recently become a subject of heightened concern and scrutiny within medical circles. Emerging evidence suggests a potential link between certain health conditions, including post-vaccine complications, and the development of unusual blood clots.

Healthcare professionals have raised concerns about the potential link between the development of these unusual clots and various health issues, including immune system suppression, viral reactivation, and cardiac damage. These concerns are further compounded by observations made during embalming procedures, where unusual blood clots have been detected, exhibiting distinct characteristics that differ from typical clots.

Notably, these observations coincide with the rollout of COVID-19 vaccines, insinuating potential correlations between vaccination and the occurrence of these atypical clots. The timing of increased deaths during embalming procedures aligns with the vaccine rollout, particularly among younger demographics targeted by vaccination campaigns. Despite these alarming findings, the response from major health agencies and mainstream media has been lacking, leaving professionals frustrated by the apparent disregard for their observations.

The reluctance of health authorities to address these concerns, coupled with efforts to suppress information, has fueled speculation and criticism regarding the transparency of vaccine-related adverse events. As more evidence surfaces, it becomes increasingly imperative to thoroughly investigate the underlying causes of these congealed clots and their potential implications for public health. The need for collaboration, transparency, and open discourse in addressing these emerging issues is paramount to ensure the safety and well-being of individuals worldwide.

Embalmers, Doctors & Scientists Are Noticing Long Congealed Clots Up To 4 Feet Long - with Dr. Ryan Cole WATCH VIDEO

Dr. Ryan Cole: "Dr. Reisa Pretorius, in her papers, has shown that you can take the spike protein in the absence of platelets, put it into platelet-poor plasma, and cause immediate clumping of the proteins in the absence of this little cascade that we always go through to form a clot. So that spike protein in and of itself, induces a highly unusual clumping of proteins in our bloodstream, and so this explains partially why we're seeing some of these outcomes."

Dr. Ryan Cole Explains the Dangers of the Spike Protein, From 'Wildfire Cancers' to Foot-Long Clots WATCH VIDEO

Key Points

- Dr. Ryan Cole discusses the evidence of increased prevalence of rare cancers and reactivation of viruses in individuals, particularly after the emergence of viruses typically found in children occurring in adults, supported by federal data sets and observations from various countries.
- There are concerns about compromised immune system functionality, with a particular focus on the innate immune system, and its potential role in enabling other infections to affect the body, as well as the adverse effects of spike protein in the body, including immune system suppression, reactivation of viruses, mitochondrial harm, cardiac damage, and clotting.
- Dr. Cole expresses concern about the potential long-term effects of certain vaccines, urges for more research, and highlights the need for alternative approaches to address adverse effects, emphasizing individual health consciousness and collaboration in addressing health issues.

Dr. Ryan Cole's Concerns About Rare Cancers and Immune Fascination: Dr. Ryan Cole, a pathologist, discusses the ongoing evidence of unusual health issues, such as rare cancers and reactivation of viruses, in individuals, especially after the emergence of viruses typically found in children occurring in adults. This increased prevalence of rare cancers is supported by federal data sets and observations from various countries. Notably, there are concerns about the compromised immune system functionality in affected individuals, with a particular focus on the innate immune system, which includes phagocytes and natural killer cells.

Dr. Cole highlights the importance of understanding the immune system's compromised state and its potential role in enabling other infections to affect the body. He emphasizes the depletion of certain protective cells and its association with an increased risk of cancer. Furthermore, Dr. Cole discusses the persistence of spike protein in the body and its adverse effects, including immune system suppression, reactivation of viruses, mitochondrial harm, cardiac damage, and clotting.

Potential Risks of Vaccine Administration and Urging for More Research: He expresses concern about the potential long-term effects of the spike protein and challenges the approval and administration of certain vaccines, citing their potential risks and limited benefits, especially for the younger population. Dr. Cole also urges for more research and public acknowledgment of the potential harms associated with the vaccines, particularly in young individuals.

Alternative Approaches for Addressing Adverse Effects: Additionally, Dr. Cole highlights the need for alternative approaches to address the adverse effects, including potential treatments and interventions that target specific inflammatory pathways, such as the use of near-infrared light to down-regulate receptors associated with inflammation in myocarditis.

Focus on Individual Health and Collaboration in Addressing Health Issues: Ultimately, he emphasizes the critical role of individual health consciousness and calls for a shift towards health and wellness, as well as the importance of collaboration, new ideas, and philanthropic support to advance research and interventions in this complex landscape.

Embalmer Reveals Unusual Vaccine-Related Clotting In 65% Of Deceased People

WATCH VIDEO

The interview between Steve Kirsch and Richard Hirschman delves into several critical points surrounding the observation of unusual blood clots seen during embalming procedures.

Observations of Unusual Blood Clots: Hirschman noticed an increase in unusual blood clotting around May or June, but it's uncertain if some started noticing it earlier during the COVID pandemic's early stages in 2020. Initially, these clots were predominantly seen in older or medically compromised individuals. Still, they started appearing in younger individuals as well. The clots observed seemed notably different from typical clots, appearing stronger, longer, and more adhesive, causing concern among embalmers who hadn't witnessed such clots before.

Vaccine Rollout and Demographic Correlation: Hirschman's observations of increased deaths for embalming coincide with the rollout of COVID vaccines. The busiest embalming period correlated with the vaccine rollout. The observed clotting in younger individuals occurred after the vaccine rollout started targeting younger demographics. While embalming of younger individuals is less frequent due to cremation trends, there's been a noted increase in deaths among those under 50, hinting at an uptick not easily captured due to cremation.

Lack of Medical Response: Despite the alarming findings, Hirschman has received minimal attention or interest from major health agencies, medical academia, or mainstream media. Even when Hirschman shared evidence with medical professionals, some remained steadfast in recommending vaccination despite witnessing the abnormal clots. The absence of significant inquiries or responses from health authorities, academia, or the media contrasts with the potential severity and implications of these findings.

Professional Concerns and Personal Stance: Hirschman, concerned about the implications of these findings, has reservations about directly involving families or publicly sharing the information for fear of backlash or upsetting the bereaved. Hirschman hasn't been vaccinated due to having prior COVID and hesitancy arising from observed post-vaccination issues.

Observations of Blood Clots and Speculation on Causes:: Hirschman highlights the frequency of finding blood clots, especially in arteries, which is uncommon and raises concerns. They've captured and shared images of these clots, seeking expert analysis from pathologists like Ryan Cole. There's speculation about medications or injectable products causing the observed blood clotting. China's role in manufacturing medications is mentioned as a potential factor. The interviewee leans towards a correlation between these unusual clots and COVID vaccines, given the timing and scale of occurrence in 2021.

Shift in Perception and Media Censorship: Those shown evidence of the unusual clots tend to shift from perceiving vaccines as safe and effective to questioning their safety or efficacy. Despite the gravity of the situation, there's been minimal attention or acknowledgment from health authorities or lawmakers. Criticism is aimed at the lack of coverage from mainstream media regarding these post-vaccine complications. Concerns are voiced about the suppression of alternative viewpoints, leading to a one-sided narrative about vaccine safety and effectiveness.

John O'Looney on blockages found in vessels of deceased COVID Vaxxed

WATCH VIDEO

The interview delves into the concerning discoveries made during embalming processes. John O'Looney, a funeral director, discusses the unexpected findings in the bodies of deceased individuals, particularly those who had received COVID vaccinations. He describes extracting strange materials—fibrous, rope-like substances—from arteries and presents images and videos as evidence. These materials, in his opinion, appeared to be present prior to the individuals' deaths, ruling out the possibility of post-mortem formation. O'Looney emphasizes the abnormality of these findings, indicating that such blockages in blood vessels are unprecedented in his 15 years of experience.

He expresses frustration over the lack of response from authorities, including the coroner's office and the British Institute of Embalmers (BIE). O'Looney states that the BIE has issued warnings against embalmers speaking out about these findings, a move he perceives as an attempt to suppress information. O'Looney calls upon fellow embalmers to share their experiences anonymously, promising confidentiality in an effort to bring attention to these unusual occurrences and prevent further deaths. He expresses concern about the increasing number of young individuals dying unexpectedly and urges for transparency and investigation into the situation.

“Special batches” of vaccines

The concept of "Special batches" of vaccines has garnered attention in recent discussions and legislative inquiries. These special batches represent a distinct category of vaccines designated for specific purposes or programs, separate from those intended for general public distribution. While the details may vary, the overarching theme revolves around the allocation of vaccines for targeted initiatives, such as internal vaccination programs for employees or other specialized campaigns. These discussions have sparked broader conversations surrounding vaccine mandates, confidentiality agreements, and concerns regarding vaccine development, safety, and distribution practices. In navigating these complex issues, there is a call for transparency, accountability, and a careful balancing of corporate interests and public health priorities.

Pfizer Employees Were Given Special Batch Vaccine, Different from What Was Distributed to the Public

WATCH VIDEO

The Australian Senate committee hearing covered several key topics, including vaccine mandates, indemnity agreements, and the development and safety of Pfizer's COVID-19 vaccine:

Pfizer's Different Batch: Pfizer imported a special batch of vaccines specifically for its colleague vaccination program for employees. The purpose of this separate batch was to ensure that vaccines for the employee program did not deplete government stocks intended for public distribution. Pfizer emphasized that the batch used for the colleague vaccination program was distinct from the one provided to the general public.

Enforcement of Vaccine Mandates: Senator Roberts inquired if Pfizer enforced its vaccine mandate for employees and whether any consequences were imposed for non-compliance. Pfizer stated that they aligned with public health guidance, allowing accommodations for medical or religious reasons, and a small number of colleagues departed the company.

Confidential Indemnity Agreements: The committee pressed on the confidentiality of indemnity agreements between Pfizer and the Australian government. Senator Roberts questioned the secrecy and asked why taxpayers, who funded the injections, were not privy to the details. Pfizer maintained that such agreements are confidential and standard practice. The committee sought information on Pfizer's contract with the government, including clauses related to indemnity and potential legal consequences for fraudulent treatment of trial data. Pfizer maintained confidentiality and declined to provide specific details.

Acceleration of Development and Long-Term Effects: Concerns were raised about the accelerated development timeline of the vaccine and whether Pfizer thoroughly researched its long-term effects and risk profile. Pfizer defended the thoroughness and comprehensiveness of the data presented to regulatory authorities, emphasizing the independent decisions made by those regulators.

Throughout the hearing, there was a recurring theme of Pfizer representatives deflecting certain questions, citing confidentiality, and emphasizing their commitment to regulatory standards and public health.

DNA Contamination

DNA contamination, within the context of vaccines, refers to the unintended presence of foreign DNA material within vaccine formulations. This issue has gained attention due to its potential implications for vaccine safety and long-term health outcomes. Several discussions and studies have examined the phenomenon, particularly in relation to mRNA vaccines, such as the COVID-19 mRNA vaccines.

One aspect of concern revolves around the identification of DNA contaminants in vaccine formulations. Studies have reported the presence of plasma DNA in certain vaccine samples, raising questions about the source and implications of such contamination. The discovery of foreign DNA within vaccine vials has sparked discussions regarding the potential risks associated with its integration into cellular genomes and its possible long-term effects on vaccine recipients.

Furthermore, the regulatory oversight surrounding DNA contamination in vaccines has come under scrutiny. Critics have highlighted perceived failures in regulatory processes that allowed DNA contaminants to be present in vaccine formulations. There have been calls for enhanced oversight and more robust testing protocols to ensure the safety and integrity of vaccine products.

Additionally, concerns have been raised about the potential biases in academic research and publication practices, which may hinder the reporting of negative findings related to vaccine safety. The urgency of investigating DNA contamination in vaccines is emphasized, with calls for immediate testing of vaccine batches to ensure safety and informed consent.

Intracellular Reverse Transcription of Pfizer BioNTech COVID-19 mRNA Vaccine BNT162b2 In Vitro in Human Liver Cell Line

SOURCE: https://pubmed.ncbi.nlm.nih.gov/35723296/

Key Points

- The research evaluated the COVID-19 mRNA vaccine BNT162b2 and found rapid uptake of the vaccine into human liver cells, leading to changes in gene expression of LINE-1, an endogenous reverse transcriptase. It also demonstrated that BNT162b2 mRNA can be reverse transcribed into DNA intracellularly within 6 hours following exposure, raising concerns about potential adverse effects.
- The study emphasized the need for further research to assess the vaccine's effects on genomic integrity, including whole genome sequencing of cells exposed to BNT162b2, and the investigation of potential effects on other cell types and tissues. Additionally, in vivo models were highlighted as essential to understand the impact of BNT162b2 on liver function and potential autoimmune responses.
- Overall, the research suggested the necessity for continued evaluation and monitoring of the safety and efficacy of the BNT162b2 vaccine, emphasizing the importance of long-term safety and efficacy monitoring.

Overview

Evaluation of BNT162b2 mRNA Vaccine: The research paper evaluated the COVID-19 mRNA vaccine BNT162b2 developed by Pfizer and BioNTech, focusing on its efficacy, safety, potential risks, and adverse effects. The study investigated the vaccine's impact on human liver cell line Huh7 in vitro. Results showed the rapid uptake of BNT162b2 into Huh7 cells, leading to changes in gene expression of long interspersed nuclear element-1 (LINE-1), an endogenous reverse transcriptase. The study also demonstrated that BNT162b2 mRNA can be reverse transcribed intracellularly into DNA in as fast as 6 hours following exposure. Concerns were raised about potential adverse effects, including pericarditis, arrhythmia, and hepatic effects observed in animal studies, and the need for long-term safety and efficacy monitoring. The paper also addressed the concern of potential reverse transcription and integration of the vaccine's RNA into the human genome, as well as the biodistribution of BNT162b2 and its effect on human liver cells in vitro.

Need for Further Research: The study highlighted the need for further research to assess the vaccine's effects on genomic integrity, including whole genome sequencing of cells exposed to BNT162b2, as well as the need to investigate the potential effects of BNT162b2 on other cell types and tissues. Additionally, the paper emphasized the importance of in vivo models to better understand the impact of BNT162b2 on liver function and potential autoimmune responses. The study provided evidence of the fast entry of BNT162b2 into cells and subsequent intracellular reverse transcription of BNT162b2 mRNA into DNA. Overall, the research suggested the necessity for continued evaluation and monitoring of the safety and efficacy of the BNT162b2 vaccine.

Differences in Vaccine and SARS-CoV-2 Replication Derived mRNA: Implications for Cell Biology and Future Disease

SOURCE: https://osf.io/bcsa6/

Key Points

- Codon optimization in mRNA vaccines can lead to alterations in the encoded protein conformation, potentially impacting immune regulation and disease progression.
- The increased GC content resulting from codon optimization can lead to the formation of G-quadruplex structures in mRNA vaccines, which may affect epigenetic reprogramming and immune response.
- N1-methylpseudouridine substitutions in mRNA vaccines can influence translation fidelity and Toll-Like Receptor activity, potentially complicating folding predictions and impacting spike protein translation efficiency. There are also concerns about the potential for chimeric RNAs to form with mRNA vaccines and live viruses, leading to immune de-regulation and the development of autoimmunity.

Overview

The research paper discusses the potential risks of oversimplifying the expression of SARs-CoV-2 spike protein in mRNA vaccines and the implications of codon optimization for viral mRNA vaccines. The paper highlights the dangers of codon optimization, emphasizing that even synonymous codon changes in mRNA vaccines can alter the encoded protein conformation, leading to differential protein folding and potentially impacting immune regulation and disease progression. The authors investigated the alterations in secondary structures of mRNA in SARS-CoV-2 vaccines due to codon optimization and identified a significant increase in the GC content of vaccine-derived mRNAs compared to native SARS-CoV-2 RNA sequences encoding the spike protein.

Formation of G-Quadruplex Structures: Codon optimization in mRNA vaccines resulted in an increased GC content, leading to the formation of G-quartet structures, potentially affecting epigenetic reprogramming of the cell by altering transcription, translation, and replication. The higher GC content in the vaccine-derived mRNAs led to the formation of more G-quadruplex structures, which are implicated in recruiting viral SARs Unique Domain (SUD) of Nsp3, potentially impacting immune response.

Impact of N1-Methylpseudouridine Substitutions: The paper further discusses the impact of N1-methylpseudouridine substitutions in mRNA vaccines, highlighting their potential influence on translation fidelity and Toll-Like Receptor activity. The authors pointed out that the altered base pairing from N1-methylpseudouridine may complicate the folding predictions and impact spike protein translation efficiency.

Spike Protein Expression and Chimeric Spike-Human Peptides: The paper underscores the complexity of spike protein expression from mRNA vaccines, highlighting the differences in biodistribution, translation fidelity, and duration of expression compared to natural infection. The authors also mentioned potential adverse effects of spike protein toxicity, such as coagulopathy and mitochondrial damage.

The study explores the potential for chimeric RNAs to form with mRNA vaccines and live viruses, particularly in the context of viral recombination, raising concerns about immune de-regulation and potential development of autoimmunity. The authors emphasized the need for further research to confirm pseudouridine-induced promiscuous translation or viral recombination with mRNA vaccines.

Conclusion: Overall, the research provides insights into the significant alterations in mRNA secondary structures due to codon optimization and N1-methylpseudouridine substitutions in mRNA vaccines. It emphasizes the need for further understanding of the potential risks associated with these modifications and the expressed spike proteins, particularly in the context of immune response, viral recombination, and potential long-term effects.

Dr. Phillip Buckhaults - Cancer Genomics Expert Testifies in South Carolina Senate Medical Affairs DNA Contamination in Vaccines WATCH VIDEO

Dr. Phillip Buckhaults, a biochemistry and molecular biology Ph.D. specializing in cancer genomics at the University of South Carolina, discussed various technical aspects related to DNA sequencing, specifically focusing on the Pfizer vaccine and its regulatory oversight. He mentioned his expertise in detecting foreign DNA, which was utilized in developing COVID tests during the pandemic.

Pfizer Vaccine's Efficacy and Limitations: Dr. Buckhaults concerns about the Pfizer vaccine, stating that while it was effective in preventing deaths, it did poorly in halting the pandemic. He cited early literature indicating a brief period of infection prevention, raising concerns about the vaccine's long-term efficacy.

Presence of Contaminants in Pfizer Vaccine: He revealed the presence of plasma DNA in the Pfizer vaccine, which he discovered through sequencing vials from the vaccination program in Columbia. He expressed worries about the consequences of this DNA contamination, citing potential risks of it integrating into cellular genomes, leading to long-term implications such as autoimmune responses and risks of future cancers. He emphasized the difference between DNA and RNA in terms of permanence and potential effects on the human body.

Buckhaults advocated for thorough testing of vaccinated individuals' tissues to ascertain whether the foreign DNA had integrated into their genomes, emphasizing the need for regulatory bodies to force Pfizer to remove the DNA from booster shots and future vaccines.

Regulatory Oversight and Failure: Dr. Buckhaults criticized the regulatory oversight that allowed DNA contamination in the vaccine. He also discussed the flawed application of older regulatory limits on DNA presence in vaccines, stating that the encapsulation of DNA in lipid nanoparticles could pose greater risks compared to traditional vaccines where naked DNA gets immediately degraded upon vaccination. Dr. Buckhaults emphasizes the need for enhanced oversight and thorough testing protocols for newer vaccine platforms.

Challenges in Investigating and Testing: Concerns were raised about the oversight mechanisms and the need for more robust independent investigations, including DHEC involvement and regulatory changes, to ensure independent investigation and validation of vaccine safety. Buckhaults further acknowledged the challenges due to financial and federal influence on such processes.

Academic and Publication Biases: He addressed the academic and publication biases that discourage reporting negative results, emphasizing the difficulty in publishing findings that might not align with prevailing narratives or show negative outcomes. He expressed the simplicity and affordability of conducting tests to check for the presence of DNA in vaccine vials and his personal decision not to take the vaccine unless confirmed DNA-free.

Urgency for Further Investigation: He stressed the urgency of investigating the presence of DNA contaminants in vaccines, suggesting immediate testing on vaccine batches to ensure safety and informed consent. Dr. Buckhaults proposed a quick and cost-effective method for assessing contamination levels in vaccines, advocating for precautionary measures until safety is assured.

Masks

Masks, in the context of public health, refer to various types of face coverings worn to mitigate the spread of infectious diseases, particularly respiratory illnesses like COVID-19. The use of masks has been a topic of considerable debate and scrutiny, with discussions focusing on their efficacy, potential adverse effects, and overall impact on public health strategies.

One key aspect of mask usage under examination is the concentration of carbon dioxide (CO_2) in inhaled air while wearing masks, particularly N95 masks. Studies have indicated a significant increase in CO_2 levels during mask-wearing, potentially reaching concentrations far above typical levels found in fresh air. This has raised concerns, especially for vulnerable populations such as pregnant women, children, and adolescents, regarding potential toxic effects due to prolonged exposure to elevated CO_2 levels. Animal studies have suggested adverse effects like stillbirths, birth defects, neuron damage, impaired memory and learning, and reproductive toxicity associated with chronic low-level CO_2 exposure from prolonged mask wearing.

Criticism has been directed at the lack of robust scientific evidence supporting mandatory mask mandates, especially for vulnerable subgroups. Calls have been made for further toxicological studies to better understand the effects of masks on different populations, including pregnant women and children. Additionally, there is a need for a re-evaluation of mask mandates based on scientific evidence, considering the potential negative impacts of prolonged mask use on mental and reproductive health.

Moreover, doubts have been raised regarding the efficacy of masks in diminishing the transmission of respiratory viruses like COVID-19. Experts express skepticism about the evidence supporting mask-wearing as an effective measure to slow the spread of the virus, noting challenges in isolating its impact from other control measures. Discussions have also emphasized the limited effectiveness of masks, with some experts highlighting the insufficiency of the current construction and materials to provide significant protection against virus transmission.

Possible toxicity of chronic carbon dioxide exposure associated with face mask use, particularly in pregnant women, children and adolescents – A scoping review

SOURCE: https://www.cell.com/heliyon/pdf/S2405-8440(23)01324-5.pdf

Key Points

- The paper reviews the toxicological effects of face masks on developing life, particularly for pregnant women, children, and adolescents, focusing on the increased concentration of carbon dioxide (CO2) in inhaled air, which can lead to chronic exposure to low levels of CO2. Animal studies indicated potential adverse effects, such as stillbirths, birth defects, neuron destruction, impaired memory and learning, as well as reproductive toxicity, due to prolonged mask wearing.
- The study focuses on prolonged use of N95 masks, leading to increased CO2 exposure (1.41–3.2% compared to 0.04% in fresh air). It highlights potential risks like neuron damage, impaired learning, anxiety, and stillbirths. Questioning mandatory mask use, especially for vulnerable groups, it urges further research on masks' effects on pregnant women, kids, and teens. The paper stresses the need to reconsider mask mandates based on scientific evidence, citing potential mental and reproductive health impacts on vulnerable populations.
- The paper emphasizes the need for comprehensive scientific evaluations of the potential toxicological effects of prolonged mask use, especially in vulnerable subgroups, and the importance of considering the balance between the benefits and potential risks of mask mandates, particularly in light of the possible adverse effects on mental and reproductive health in these vulnerable populations.

Introduction: The research paper delves into the impact of wearing face masks, especially N95 masks, on the levels of carbon dioxide (CO2) inhaled. It highlights a significant increase in CO2 concentration during mask-wearing, potentially reaching levels between 1.41% to 3.2% in the inhaled air, far higher than the typical 0.04% in fresh air. The authors express concern, especially for pregnant women, children, and adolescents, emphasizing potential toxic effects due to elevated CO2 exposure. Animal studies indicated various adverse effects like stillbirths, birth defects, neuron damage, impaired memory and learning, as well as reproductive toxicity linked to chronic low-level CO2 exposure. The paper underscores the developmental risks associated with prolonged mask wearing in these vulnerable groups.

Lack of Scientific Evidence: Furthermore, the authors raised concerns regarding the lack of scientific evidence supporting the mandatory use of masks, especially for vulnerable subgroups. They emphasized the need for further toxicological studies, particularly focusing on the effects of masks on pregnant women, children, and adolescents. The paper also called for a re-evaluation of mask mandates based on scientific evidence, highlighting the potential negative impact of prolonged mask use, especially in vulnerable subgroups.

Conclusion: The paper highlights the necessity for thorough scientific assessments regarding prolonged mask use, especially among vulnerable groups like pregnant women, children, and adolescents. It stresses the importance of weighing the benefits against potential risks, particularly concerning mental and reproductive health in these populations. Discussing the toxicological effects of masks, especially CO2 rebreathing, it suggests a potential link between widespread mask use and increased stillbirths and cognitive issues in pandemic-born children. Concerns arise regarding exceeding recommended CO2 limits during mask wearing and the long-term impacts. The paper urges further research, advocating experiments on exposure times and biochemical measurements, specifically among vulnerable groups. It underscores the necessity to refocus research on current mask-related CO2 increases. Lastly, the study notes the lack of specific funding and competing interests, highlighting the urgent need for more comprehensive studies to comprehend masks' potential risks and benefits concerning toxicological effects and viral transmission prevention.

No proof face masks ever worked against Covid, claims UKHSA boss who warns they may have even had OPPOSITE effect on spread through 'false sense of security'

29 November 2023

SOURCE: Daily Mail

Key Points

- Professor Dame Jenny Harries, head of the UK Health Security Agency, expressed uncertainty about the effectiveness of face masks in slowing the spread of Covid-19, citing challenges in isolating their impact from other control measures.
- She criticized the government's advice on mask-making, noting that using two pieces of cloth was ineffective and that at least three layers were required for a small effect on virus transmission.
- Dame Jenny emphasized that mask effectiveness varies with materials used, highlighted the importance of wearing them properly, and expressed concerns about promoting mask-wearing leading to a neglect of other crucial preventive measures such as social distancing.

Synopsis

The article discusses the statement made by Professor Dame Jenny Harries, the head of the UK Health Security Agency and former deputy chief medical officer of England, regarding the effectiveness of face masks in slowing the spread of Covid-19. She expressed uncertainty about the evidence supporting the reduction of virus transmission through mask-wearing, citing challenges in separating their impact from other Covid-19 control measures. Additionally, she criticized the government's advice on mask-making, stating that using two pieces of cloth was ineffective, as studies indicated that at least three layers were required for a small effect on transmission. Furthermore, Dame Jenny highlighted that mask effectiveness varies with the materials used and emphasized the importance of wearing them properly to be effective. She also raised concerns that promoting mask-wearing might have given people a false sense of security, potentially leading to a neglect of other crucial preventive measures, such as social distancing. Additionally, she emphasized the need for evidence-based interventions to avoid risk compensation and maintain a central position in the debate on face coverings. Dame Jenny also expressed concerns about the economic and safety implications of promoting face coverings without robust evidence to support their effectiveness. She highlighted the risk of people believing they could return to normalcy by simply wearing face coverings made from inadequate materials, emphasizing the importance of evidence-based public health interventions. Overall, the article highlights Dame Jenny's skepticism about the effectiveness of face masks in controlling Covid-19 transmission and the need for evidence-based approaches to public health interventions.

Excess Deaths

Excess deaths refer to the number of deaths that exceed the expected number based on historical data, considering factors like seasonality and population trends. This concept has become particularly important in the context of the COVID-19 pandemic and its aftermath, as it helps to assess the broader impact of the virus and the measures taken to control it, including vaccinations.

The analysis of excess deaths provides a more comprehensive picture of mortality changes, revealing the true extent of the pandemic's impact beyond the officially reported COVID-19 deaths. It encompasses deaths directly caused by the virus and those resulting from indirect effects, such as overwhelmed healthcare systems, delayed medical treatments, and socioeconomic disruptions.

During the COVID-19 pandemic, there have been significant concerns and debates about the accuracy of reported death tolls. Some claim that official counts are inflated, while others suggest that the actual death toll is much higher when considering unreported cases. Additionally, the introduction and widespread administration of COVID-19 vaccines have introduced further complexities in understanding excess deaths. Some analysts and whistleblowers have raised concerns about vaccine-related adverse effects and their potential contribution to excess deaths. These concerns include sudden deaths in vaccinated individuals, unusual substances found in autopsies, and an observed rise in neonatal and postnatal deaths during periods of increased vaccination among pregnant women.

Data from various regions have shown significant increases in certain types of deaths following vaccine rollouts, prompting calls for further investigation into the potential links between vaccination and excess deaths. For instance, increases in cancer deaths among younger age groups have been noted, with some experts suggesting a possible connection to the COVID-19 vaccines. Furthermore, there have been observations of increased mortality rates among infants and a higher incidence of specific cancers, raising questions about the long-term impacts of the vaccination campaigns.

Transparency in data reporting is crucial in understanding and addressing excess deaths. However, there have been concerns about the lack of transparency, particularly regarding the vaccination status of deceased individuals and the suppression of information related to vaccine adverse events. This has led to calls for more rigorous and independent research to fully understand the factors contributing to excess deaths and to inform public health policies effectively.

John O'Looney: "Number Of Baby Deaths Has Gone Through The Roof"

WATCH VIDEO

John O'Looney, a funeral home whistleblower, discusses various concerning aspects of the COVID-19 pandemic:

Disputed Death Toll: O'Looney contested the official COVID-19 death count, suggesting it was inflated, and believes the actual numbers are significantly lower.

Vaccine Concerns: He suggests that vaccines, rather than the virus itself, caused many deaths. He observed sudden deaths in vaccinated young individuals and highlights concerns about vaccine-related fibrous substances found in deceased individuals' arteries.

Autopsy Findings: O'Looney mentions unusual substances found in vaccinated individuals during autopsies and criticizes the lack of investigation by medical authorities.

Increased Young and Baby Deaths: He notes a rise in deaths among young people, including athletes, and an unprecedented number of baby deaths, highlighting concerns about hospitals sending babies directly to crematoriums without involving funeral directors.

Information Suppression: O'Looney suspects intentional suppression of information about child deaths and vaccine-related adverse events to conceal alarming trends.

Silence of Medical Professionals: He criticizes medical professionals and authorities for not addressing concerning findings and events related to vaccines.

Deaths of Scottish babies

SOURCE: https://www.hartgroup.org/deaths-of-scottish-babies/

Key Points

- **Increase in neonatal and postnatal deaths** in Scotland in 2021 coincided with the period when pregnant women were being vaccinated against COVID-19. Public Health Scotland refused to investigate the potential relationship between the vaccine and the increased deaths due to concerns about vaccine confidence.
- **Evidence of excess deaths:** During the vaccination period, there were 35 additional neonatal deaths and 30 additional postnatal deaths compared to historical rates. The excess death rate was calculated to be 1 extra death for every 690 doses of the COVID-19 vaccine administered.
- **Lack of transparency in data:** Data on the vaccine status of the mothers of the deceased babies has not been provided, raising concerns about the transparency of reporting. Additionally, the National Records of Scotland's data showed a rise in mortality rates for infants aged 0, further supporting the findings of excess deaths during the post-vaccination period.

The article discusses concerns about the impact of COVID-19 vaccination on infant mortality in Scotland. It notes a significant increase in neonatal and postnatal deaths during the vaccination period, with 35 additional deaths compared to historical rates. The excess death rate is calculated to be 1 extra death for every 690 doses of the vaccine administered. Despite Freedom of Information requests, data on the vaccine status of mothers of deceased babies has not been provided, raising transparency concerns. The article also highlights a rise in mortality rates for infants aged 0, indicating potential issues - along with a 27% increase in England's infant mortality rate. The article emphasizes the human impact, citing a high estimate of life lost and raising questions about data and transparency regarding the vaccine's impact on infant mortality.

Testimony from Dr. McCullough on COVID-19 Vaccines, Pennsylvania State Capital (2023)

WATCH VIDEO

Dr. Peter McCullough's presentation at the Pennsylvania State Capital covers a wide range of topics related to COVID-19, vaccines, and their effects. He presents several key points about the significant number of excess deaths and adverse effects among vaccinated individuals:

Vaccine Adverse Effects: Dr. McCullough focuses on adverse effects, stating that most Americans have received at least one shot but argues that the actual number might be lower than CDC estimates. He highlights significant discrepancies in reporting and suggests that 25% of the population is unvaccinated and available for study.

Vaccine Injuries and Deaths: He points out that by January 22nd, 2021, the Vaccine Adverse Event Reporting System (VAERS) had recorded 182 deaths post-vaccination, far exceeding the average number of deaths for widely administered vaccines in a year. He criticizes the FDA and CDC for their role in overseeing vaccine safety and claims there was a cover-up regarding adverse effects.

Excess Deaths Among Vaccinated Individuals: Dr. McCullough presented data suggesting that in countries like the UK, Australia, and South Africa, where comprehensive vaccination data was available, a significant portion of hospitalized and deceased individuals from late 2021 through 2022 were fully vaccinated. For instance, in New South Wales, Australia, about 99% of those hospitalized and deceased were fully vaccinated. Similarly, he pointed out that the United States, despite being heavily vaccinated, led the world in COVID deaths.

Other topics discussed include:

Emergency Use Authorization (EUA) of Vaccines: Dr. McCullough discusses the emergency use authorization of Pfizer's vaccine and emphasizes that this mechanism was traditionally reserved for military means, not for public usage. He highlights the rapid development of mRNA vaccines.

Categorization of Vaccine Injuries: Dr. McCullough categorizes adverse effects into four domains: cardiovascular, neurologic, thrombotic, and immunologic. Within the cardiovascular domain, he discussed myocarditis, a condition involving heart inflammation linked to the COVID-19 vaccines. He noted that the spike protein installed by genetic vaccines damages the heart, causing issues such as heart attacks, strokes, and accelerated atherosclerotic cardiovascular disease. Dr. McCullough also addressed the thrombotic category, emphasizing that the vaccines induce blood clots through the spike protein, causing potentially fatal clotting conditions. He cited studies detailing large and resistant blood clots forming in vaccinated individuals, leading to severe health complications.

Long-term Effects of Vaccines: Dr. McCullough raises concerns about long-term effects, indicating that certain adverse effects may persist for years, such as blood clots in the retinal arteries and veins. Lot-to-lot variability in vaccines was highlighted as a significant factor in triggering adverse reactions in some individuals. Dr. McCullough referenced Schmeling's data, suggesting that different vaccine lots could lead to various side effects.

Persistence of Spike Proteins in the Body: Research by Bruce Patterson showed the persistence of spike proteins in white blood cells months after vaccination or severe COVID infection. This suggests that spike proteins, as well as messenger RNA, could remain in the body for an extended period, possibly months or even years.

Concerns About mRNA in Food Supply: Studies have demonstrated that mRNA can cross the gastrointestinal tract, leading to concerns about potential ingestion of genetic material through the food supply. The USDA is involved in developing genetic vaccines for consumption in livestock and plant crops, which raises concerns about unintended consequences and long-term effects on human health.

Risk of Blood Transfusions and Shedding: He addressed concerns about the risk of exposure to vaccinated individuals through the blood supply. While there's no confirmed transference of mRNA or spike protein during blood transfusions, research showed messenger RNA in breast milk, indicating a potential risk of ingestion and absorption by infants.

Challenges with Mask Mandates: He questioned the efficacy of mask mandates, citing a Cochrane analysis suggesting that public masking had no significant impact on disease spread. He criticized the emphasis on masks while more crucial aspects, like early treatment, were overlooked.

New Report: Young People Dying of Cancer at 'Explosive' Rates, UK Government Data Show

SOURCE: https://childrenshealthdefense.org/defender/young-people-cancer-death-uk-edward-dowd-analysis/

Key Points

- Data analyst Edward Dowd's report highlights a significant increase in cancer deaths among 15- to 44-year-olds in the U.K. following the rollout of COVID-19 vaccines.
- The analysis is based on U.K. government data and shows a sharp rise in cancer deaths among young people, particularly in various types of cancer such as breast cancer, pancreatic cancer, colon cancer, melanomas, and brain cancer.
- The report emphasizes the need for further investigations into the potential link between the increase in cancers and the COVID-19 vaccines. Experts express concerns about the rise in cancer cases and stress the importance of independent research to guide public policy.

Overview

The article discusses a report by data analyst Edward Dowd, which shows a significant increase in cancer deaths among 15- to 44-year-olds in the U.K. following the rollout of COVID-19 vaccines. Dowd's analysis is based on U.K. government data and highlights a sharp rise in cancer deaths among young people, prompting concerns and calls for further investigation. The study indicates that from late 2021, there was a substantial increase in cancer deaths in individuals aged 15 to 44 in the U.K., with specific increases in various types of cancer such as breast cancer, pancreatic cancer, colon cancer, melanomas, and brain cancer.

Observations in the Data

Dowd's research team noticed a striking pattern in the data, with a significant number of deaths among young people remaining uncoded, which is indicative of excess deaths in this age group. The report highlights a statistically significant increase in malignant neoplasm deaths among young individuals and emphasizes the need for further investigations and analysis at a population level to clarify if the anecdotal evidence is abnormal. The research also points to the potential link between the rise in cancers and the COVID-19 vaccines, suggesting that the relationship between the two is worth examining.

Additionally, the report confirms similar data on sharp cancer death increases reported by researchers, clinicians, and cancer specialists in the U.S., U.K., and across the Western industrialized world following the global rollout of the experimental Pfizer and Moderna mRNA vaccines. It notes concerns about the severity and increase in fatal breast cancers and other cancers in young individuals. The rise in "turbo cancers" and the faster growth of tumors, as well as the increase in various types of cancer occurring in the same individual, are highlighted as particularly distressing trends.

Insights from Medical Experts

The article also includes insights from experts such as Dr. Chris Flowers, Dr. Pierre Kory, and David Wiseman, all of whom express concerns about the increase in cancer cases and emphasize the need for further research and investigation into the potential connection between COVID-19 vaccines and the rise in cancers. Overall, the report and experts cited in the article call for a reality check for health professionals and stress the importance of independent research to guide public policy and provide high-quality research to individuals and institutions seeking similar outcomes.

Relevant Headlines

This section encapsulates a myriad of news articles, offering a stark contrast to the narratives commonly disseminated by official or governmental sources regarding the COVID-19 pandemic. Originating from various mainstream publications, these articles present a tapestry of diverging viewpoints and alarming revelations.

Each article serves as a fragment, unveiling facets that challenge the conventional discourse. From concerns raised by the Surgeon General in Florida about adverse events linked to mRNA COVID-19 vaccines to discussions on post-vaccination illness resembling Long Covid, these headlines echo a chorus of dissenting perspectives.

The discourse extends to topics like myocarditis and pericarditis concerns post-vaccination, the alarming increase in non-Covid deaths at home during the pandemic, and investigations into the synthetic spike protein's impact, potentially contributing to excess deaths and hospitalizations.

Moreover, these headlines delve into leaked documents raising concerns about mRNA stability in early vaccine batches, the potential risks of mask-wearing on children's health, and shocking microscopy photos of blood clots extracted from those who passed away suddenly, raising questions about their composition and origin.

This collection of "Relevant Headlines" serves as a mosaic, reflecting diverse angles and revelations that often stand in contrast to the predominant narrative. These articles underscore the significance of critically evaluating multiple perspectives and the necessity of comprehensive and transparent discourse within the context of public health emergencies.

Health Alert on mRNA COVID-19 Vaccine Safety

February 15, 2023

SOURCE: FloridaHealth.gov

The State Surgeon General in Florida has issued a health alert regarding a significant increase in reports to the Vaccine Adverse Event Reporting System (VAERS) after the COVID-19 vaccine rollout. In Florida, there was a 1,700% increase in VAERS reports, compared to a 400% increase in overall vaccine administration. Reports of life-threatening conditions saw a 4,400% increase. The Surgeon General has communicated these findings to the FDA and CDC, emphasizing the need for additional transparency. Studies cited indicate excess risks of serious adverse events associated with mRNA COVID-19 vaccines, including coagulation disorders, acute cardiac injuries, and more. The State of Florida emphasizes the importance of accurate communication of risks and benefits by healthcare providers and remains committed to protecting communities from COVID-19.

Rare link between coronavirus vaccines and Long Covid–like illness starts to gain acceptance

3 JUL 2023

SOURCE: Science.org

The article discusses the emerging recognition of a possible link between COVID-19 vaccines and a post-vaccination illness that resembles Long Covid. Termed "Long Vax" by some, the condition manifests as persistent headaches, fatigue, abnormal heart rate, and blood pressure, with potential connections to small fiber neuropathy and postural orthostatic tachycardia syndrome (POTS). Despite the rarity of cases, researchers are studying these complications, including potential immune system overreactions and the impact of vaccination on POTS. Concerns about vaccine mistrust and the need for further studies are highlighted. The diagnostic and treatment challenges for affected individuals, including plasma exchange and experimental treatment regimes, are also discussed. Finally, the article addresses the urgency in understanding this subset of post-vaccination patients and providing support for their unique challenges.

Myocarditis began with vaccine rollout

January 18, 2023

SOURCE: HARTgroup.org

The article discusses concerns raised by the HART group regarding myocarditis and pericarditis as potential post-vaccination heart issues. The main points emphasized include the attribution of myocarditis to vaccine injections rather than viral infections and the need to properly measure the wider harm caused by these conditions. Data from multiple sources supports the assertion that the injections, not the viral infections, are causing myocarditis. Furthermore, there is a discussion about the extent of harm done to hearts and the potential long-term effects of heart damage, including the risk of sudden cardiac arrest. The article presents findings from studies measuring subclinical heart damage in teenagers post-vaccination, indicating a higher rate of harm than previously recognized. Additionally, there is a critique of contradictory English data, specifically examining epidemiological studies from Oxford and ONS data on the cause of death, which raises questions about the accuracy of reported figures. The article argues that myocarditis incidence has risen only with the arrival of the vaccination program and that the incidence after infection seems to be higher in vaccinated individuals. The need for more comprehensive and transparent data on myocarditis rates in the unvaccinated population and the potential long-term outcomes of subclinical heart damage is underscored.

Nearly 90,000 more people died at home from non-Covid causes in pandemic

20 September 2022

SOURCE: Telegraph.co.uk

The article highlights a concerning increase in non-Covid deaths at home during the pandemic, with nearly 90,000 more people dying at home from non-Covid causes. The Office for National Statistics reported a 30.2% increase in deaths in private homes between March 2020 and June 2022, while deaths in hospitals and hospices for non-Covid reasons decreased. The data revealed increases in deaths from heart disease, dementia, and Alzheimer's disease, as well as cancers during the pandemic period. There has also been a worrying rise in non-Covid excess deaths in recent months, with an increase of 15.4% in May and 8.6% in June compared to the five-year average. Many of these excess deaths were not due to coronavirus. The article also discusses the rise in cardiovascular deaths at home and the need for urgent research to understand the reasons behind it. The Office for National Statistics suggested the possibility of "mortality displacement," with the number of deaths higher than average due to below-average deaths earlier in the year.

The impact of synthetic spike protein

October 5, 2022

SOURCE: HARTgroup.org

The article discusses the potential impact of synthetic spike protein, including from COVID-19 vaccines, on non-COVID deaths and hospitalizations. It highlights a rise in excess deaths and hospital pressures in Europe, Australia, and the USA, even in areas with minimal prior COVID-19 cases. The paper questions the role of spike protein exposure from either infection or injection in contributing to conditions such as heart attacks and strokes, possibly with a time lag of around six months. The article also notes a significant increase in non-COVID-related hospital admissions, particularly for cardiac and respiratory issues, and abnormally high ambulance response times, especially in vaccinated individuals. It emphasizes the need for further investigation into the potential link between spike protein exposure and adverse health outcomes. The diverse geographic locations and varying COVID-19 trajectories in the UK, Australia, and the USA serve as evidence to suggest a common factor unrelated to COVID-19 but possibly linked to the spike protein. The paper raises concerns about the lack of shared data that could disprove the hypothesis and calls for increased transparency and further research to explore the potential connection between synthetic spike protein exposure and adverse health effects.

The EMA COVID-19 Data Leak, And What It Tells Us About mRNA Instability

10 March 2021

SOURCE: British Medical Journal

EMA's Concerns Regarding mRNA Stability: The article examines leaked documents from the European Medicines Agency (EMA) which revealed concerns about the stability of mRNA in early commercial batches of Pfizer-BioNTech's COVID-19 vaccine. The leaked documents showed that regulators had concerns about the lower than expected levels of intact mRNA in the vaccine batches, leading to questions about the assessment of this novel vaccine platform. EMA identified a significant difference in the percentage of RNA integrity between clinical and proposed commercial batches, and the agency had major concerns regarding the implications of this loss of RNA integrity on the safety and efficacy of the vaccine.

EMA Authorization Decision: Despite these concerns, the EMA authorized the vaccine in December, but it's unclear how the agency's concerns were addressed. The leaked documents raised broader questions about the complexities of assuring quality for novel mRNA vaccines, including the quantification and integrity of mRNA, carrier lipids, and the distribution of particle sizes. RNA instability, a significant variable for mRNA vaccines, received scant attention in the clinical community, and there is a lack of specific regulatory guidance for mRNA-based vaccines.

Information Gaps and Regulatory Concerns: The research also highlighted the lack of information from regulatory authorities and vaccine manufacturers regarding the acceptable percentage of mRNA integrity for COVID-19 vaccines. The leaked correspondence revealed that specific information related to the acceptability criteria, including the percentage of mRNA integrity, was considered commercially sensitive and was not shared with the research team. The article discusses concerns raised by experts about the biodistribution of lipid nanoparticles used in the vaccines and emphasized the need for pharmacokinetic studies to determine potential cytotoxicity and macroscopic toxicity.

Wearing a mask can expose children to dangerous levels of carbon dioxide in just THREE MINUTES, study finds

5 July 2021

SOURCE: Daily Mail

The research study, led by Dr. Harald Walach from the Poznan University of Medical Sciences, investigated the impact of wearing masks on children's exposure to carbon dioxide levels. The study included 45 children and found that even a few minutes of wearing a mask could expose children to dangerous levels of carbon dioxide. The younger children were exposed to higher levels of carbon dioxide compared to older children, with some reaching levels up to twelve times the acceptable limit within just three minutes of wearing a mask. The research revealed that every child in the study recorded at least three times the appropriate healthy levels of carbon dioxide, and younger children tended to have higher levels on average. Additionally, the study found that younger children had more complaints, which were often side effects of increased carbon dioxide levels. The findings indicated that the carbon dioxide levels of children in all age groups exceeded healthy levels, with the youngest children recording around 1.7 percent carbon dioxide and the oldest recording around 1.4 percent. The study was limited by its small sample size, and the research was conducted in a laboratory setting, which may have affected the children's breathing patterns. The study highlighted the potential negative impact of mask-wearing on children, particularly with little benefit in terms of COVID-19 spread, as younger children were unlikely to spread the virus at school. Overall, the study suggested that the requirement for children to wear masks in schools, while well-intentioned, may have led to harmful effects on children without significant benefits.

EXCLUSIVE: Shocking microscopy photos of blood clots extracted from those who “suddenly died” – crystalline structures, nanowires, chalky particles and fibrous structures

06/12/2022

SOURCE: Natural News

The article presents a series of microscope photos of unusual clots found in adults who died suddenly, often following COVID-19 vaccinations. These clots, extracted from patients shortly after death, exhibit properties such as toughness, fibrous strands, and repeating patterns resembling circuitry. The photos also show crystal-like structures, chalky particles, and nanowire-like formations. The author emphasizes that these clots are not normal blood clots and are being constructed inside blood vessels. The embalmer who provided the samples confirmed that they are not blood vessels or other tissues. The author acknowledges the need for further research to confirm the composition and function of these structures and suggests that they may be a result of mRNA gene therapy injections. The author expresses concern that people who have received these injections may be developing similar fibrous structures, potentially leading to major health issues. The article concludes with an invitation to listen to a podcast for more detailed discussion and emphasizes the need for independent analysis due to the perceived censorship in the scientific community. Overall, the article raises questions about the nature and potential risks of these unusual clots in the context of mRNA vaccinations and calls for further investigation.

Pfizer ‘Chose Not To’ Tell Regulators About SV40 Sequence in COVID Shots: Health Canada Official

23/04/2024

SOURCE: Epoch Times

ARCHIVED Archive.org

According to the article, a senior Health Canada official, Dr. Dean Smith, revealed that pharmaceutical company Pfizer made a conscious decision not to inform regulators, including Health Canada, the FDA, and the EMA, that its mRNA COVID-19 vaccine contained a DNA sequence from the Simian Virus 40 (SV40). This information was obtained through an access-to-information request. Dr. Smith expressed concerns about the presence of the SV40 sequence, stating that it is "active in mammalian cells" and that Pfizer's claim that it is not material to the plasmid manufacturing is an "overt lie." The article also discusses concerns raised by scientists about the potential for the unintended DNA in the mRNA shots to integrate into the human genome and cause issues like cancer. Health Canada has maintained that the SV40 sequence is a "residual DNA fragment" that is inactive and has no functional role, but this view has been challenged by experts like Kevin McKernan and Dr. Philip Buckhaults.

Additional Insight

In this final chapter, a spectrum of expert voices offers a mosaic of insights that challenge established narratives surrounding the COVID-19 pandemic. This section stands as a culmination of diverse, well-grounded perspectives, enriching the discourse with viewpoints that often stray from—and outright contradict—mainstream conventions.

What distinguishes this chapter is the breadth of opinions and expertise it encompasses. From healthcare professionals to researchers and dissenting voices less heard in mainstream discourse, this collective compendium presents a panorama of ideas that deviate from conventional narratives, offering readers a nuanced and comprehensive understanding of the pandemic's complexities.

Crucially, this section encourages critical examination and reflection on the multifaceted dimensions of the pandemic. It serves as a platform that embraces the intellectual diversity necessary to navigate this expansive and intricate landscape of viewpoints and conclusions. Some of these viewpoints might touch upon previously discussed topics in this paper, yet they approach them from fresh vantage points or utilize different methodologies, offering alternative insights that supplement the earlier analyses.

Ultimately, this chapter functions as an intellectual forum, fostering an environment where diverse perspectives coalesce to enrich our collective understanding of this worldwide scenario. Readers are invited to actively engage with these varied perspectives.

Dr. John Campbell: Covid vaccine caused myocarditis

WATCH VIDEO

Dr. John Campbell's presentation primarily focuses on the incidence and severity of myocarditis (inflammation of the heart muscle) post-COVID vaccination, highlighting data from studies in Korea and Denmark. The discussion centers on vaccine-related myocarditis, particularly in young men, as a concerning side effect.

Myocarditis Severity: Contrary to claims of mildness, approximately 19.8% of reported cases of vaccine-related myocarditis were severe, challenging the perception of the condition as benign.

Study Details: The Korean study involved a comprehensive analysis of 44 million vaccinated individuals, emphasizing the rigor of the research and the conservative approach used to diagnose myocarditis, leading to potentially underreported cases.

Demographics: Incidence rates of vaccine-related myocarditis were notably higher in males, especially in the age group of 12 to 17. Women over 70 also experienced cases, albeit at a lower rate.

Vaccine Types: Differences in myocarditis incidence were observed between vaccine types, with mRNA vaccines (Moderna and Pfizer) showing higher rates compared to adenovirus vector vaccines (AstraZeneca, Johnson & Johnson).

CDC Guidelines: Despite the data suggesting higher risks, the Centers for Disease Control (CDC) continue to recommend COVID vaccination for adolescents, prompting criticism and concern over the delay in updating guidelines.

Adverse Effects: Severe outcomes such as sudden cardiac deaths and the need for heart transplants were reported, predominantly in younger men under 45 years old.

Symptoms and Timing: Common symptoms included chest pain, typically occurring within a few days after vaccination, with a notable risk period of the first and second day post-vaccination.

Long-term Effects: While acute episodes of myocarditis seemed to subside after a certain period, concerns remained regarding potential long-term consequences, despite authorities' assertions of mild and transient effects.

Recommendation: Dr. Campbell advises seeking medical advice from healthcare professionals for individual health concerns and emphasizes the need for the CDC to update guidelines in light of the accumulating data.

The presentation underscores the urgency of reevaluating vaccination recommendations, especially for younger demographics, due to the severity of vaccine-related myocarditis cases observed in the studies from Korea and Denmark.

Real time obstetrician/gynecologist's data on new patients and miscarriages for 2021 and 2022 (and now 2020 for baseline)

SOURCE: https://jessicar.substack.com/p/real-time-obstetriciangynecologists

Dr. Jessica Rose's article presents data collected by an obstetrician/gynecologist regarding new patient counts and miscarriage rates from 2020 to 2022. The primary focus revolves around observing the trends in new patients and miscarriages, particularly comparing 2021 to 2022, with a reference to potential influences such as lockdowns and injections. In summary, Dr. Rose's analysis highlights a notable decline in new patient counts and a simultaneous increase in miscarriage rates between 2021 and 2022. The article hints at a potential association between the observed trends and the rollout of COVID-19 vaccines, prompting further investigation into this correlation.

Key Points

- The research paper analyzes obstetrician/gynecologist's data on new patients and miscarriages for the years 2021 and 2022, and compares it to 2020 data. It shows a decrease in the number of new patients in 2021 and 2022 compared to the average in 2020.
- The data reveals that the number of miscarriages is higher in 2022 compared to 2021, with the miscarriage rates being twice as high in 2022. The paper also discusses the comparison of miscarriage rates since the rollout of COVID-19 injectable products in the US and presents cumulative losses against cumulative new patients for 2021 and 2022.
- The author suggests a potential association between the increase in miscarriages and the COVID-19 injections, speculating that the decrease in new moms in 2022 may be related to the COVID-19 injections rather than lockdowns. The paper concludes by calling for further investigation into this relationship and includes product monographs for Pfizer, Moderna, and Janssen, as well as a suggestion to register data.

New Patient Counts:

Figure 1 and 2 display the monthly counts of new patients from 2021 and 2022 compared to the 2020 average. Throughout both years, the number of new patients consistently falls below the 2020 average, suggesting a decline in pregnancies or women seeking obstetric/gynecologic care. A speculation is made regarding the possible reasons behind the decline, including external factors like global unrest due to perceived threats.

Miscarriage Rates:

Figure 2 illustrates the absolute counts of miscarriages for 2020, 2021, and 2022. The data indicates higher miscarriage numbers for most months in 2021 and 2022 compared to 2020, with a few exceptions.

Figure 3 normalizes the miscarriage data by the number of new patients, revealing that the miscarriage rates in 2022 are twice as high as those in 2021 on average.

Figure 4 compares the miscarriage rates between December 2021 and November 2022, hinting at a potential correlation between increased miscarriages and the period following the rollout of COVID-19 vaccines in the US.

Cumulative Analysis:

Figure 5 depicts cumulative losses (miscarriages) against cumulative new patients for both 2021 and 2022, offering a concise comparison of cumulative trends between the two years.

Speculations on Influences:

Dr. Rose questions the potential factors contributing to these trends, initially considering lockdowns as a possible explanation for the decline in pregnancies seen in 2021. However, a shift in focus occurs as she doubts that the decline in 2022 could be attributed solely to lockdowns. She introduces the idea that it might be associated with injections (presumably COVID-19 vaccines) rather than lockdown measures.

Additional References:

The article includes a reference to product monographs related to vaccine safety for Pfizer, Moderna, and Janssen products in pregnant women, hinting at a connection between the vaccines and the observed trend in miscarriages.

Dr. Tess Lawrie Interviews Dr. David Cartland: No More Injections! WATCH VIDEO

Dr. David Cartland, a General Practitioner from Cornwall, expressed concerns about the COVID-19 genetic vaccines in an interview with Dr. Tess Lawrie. He outlined his journey from initially following mainstream guidance to becoming critical of the COVID vaccines.

Cartland's concerns stemmed from his observations during the pandemic. Despite media reports of a severe crisis, he noticed a lack of alignment between the portrayed situation and the reality in clinical settings. He questioned the rushed vaccination process, particularly the lack of informed consent, inadequacy of information about adverse reactions, and the novel mRNA technology used in the vaccines.

His reservations grew as he encountered instances of unqualified personnel administering vaccines and insufficient data on vaccine safety. Cartland highlighted adverse reactions post-vaccination, the ineffectiveness of the vaccines in preventing transmission and severe cases, especially among the vaccinated population.

He emphasized ethical concerns regarding vaccinating children, pregnant women, and healthy adults unnecessarily. He urged medical professionals to question, research, and critically evaluate available data, advocating for patient safety and informed consent.

Despite facing professional ostracization for his dissenting views, Cartland stood firm, recommending alternative measures like supplements and therapies to minimize potential vaccine side effects. He called for collective action among healthcare professionals to create a platform for open discussion and support for those questioning the prevailing narrative on COVID vaccines.

Cartland's final message cautioned against blindly following booster schedules and urged the public to reconsider taking additional vaccine doses, advising reliance on natural immunity and traditional remedies if infected.

In essence, Dr. Cartland's interview highlighted his transition from vaccine acceptance to skepticism, stressing the importance of informed consent, critical evaluation, and the need for a collective voice among healthcare professionals in ensuring patient safety.

Press conference on the letter from EMA, by Forum for Democracy in the European Parliament

WATCH VIDEO

Key Points

- The European Medicines Agency (EMA) indicated that COVID vaccines were authorized solely for individual immunization and not for controlling infections. It emphasized the lack of data on infectiousness and the potential risk of infection for vaccinated individuals.
- Concerns were raised about misinformation, inadequate information for informed consent, potential risks and side effects of the vaccines, and the need for accurate and transparent reporting of adverse events. Specific issues included the classification of the vaccines as gene therapy, potential long-term effects, and batch dependency safety issues.
- The conference called for immediate action from the EMA to address vaccine safety concerns, ensure accurate reporting of adverse events, and provide appropriate regulatory actions to ensure public safety. The emphasis was on thorough monitoring, accurate information for informed consent, and transparency in reporting adverse events.

Overview

The press conference discussed concerns about the safety and efficacy of COVID vaccines, focusing on the responses received from the European Medicines Agency (EMA) related to COVID vaccine authorizations and safety issues. The conference participants, including Marcel de Graaf, Joachim Kues, Willem Engel, Fibika Mannetje, and Mark Schmeling, highlighted key findings and concerns.

EMA Response: The EMA's response indicated that COVID vaccines were authorized solely for individual immunization and not for controlling infections. It also highlighted the lack of data on infectiousness and emphasized that vaccinated individuals could still be at risk of infection. The conference participants expressed concerns about misinformation, inadequate information for informed consent, and the potential safety issues associated with different vaccine batches.

Concerns and Risks: Willem Engel emphasized the EMA's admission that the information provided to the public was inadequate for informed consent and highlighted the potential risks and side effects of the vaccines. The participants raised concerns about the classification of the vaccines as gene therapy, the potential long-term effects, and the need for accurate and transparent reporting of adverse events.

Fibika Mannetje discussed the study on batch dependency safety issues, indicating patterns of side effects associated with different vaccine batches. Concerns about vaccine batches showing different patterns of side effects raised questions about quality control, efficacy, and transparency. Some batches showed higher mortality risks, indicating a lack of uniformity and undisclosed risks associated with different batches.

Additional Concerns: The participants also raised concerns about the lengthy and complex information provided by vaccine manufacturers, the potential risks associated with specific vaccine batches, and the need for ongoing monitoring and assessment of vaccine safety.

Call for Action: The conference called for the EMA to take immediate action, address the concerns related to vaccine safety, and ensure accurate reporting of adverse events. The participants expressed their intention to send a second letter to the EMA to address the issues raised.

Conclusion

In conclusion, the press conference highlighted significant concerns regarding COVID vaccine safety, informed consent, and transparency in reporting adverse events. The participants emphasized the need for thorough monitoring, accurate information for informed consent, and appropriate regulatory actions to ensure public safety.

CLOSING REMARKS

In conclusion, this expansive compendium offers a comprehensive exploration of the COVID-19 pandemic, drawing from a diverse array of perspectives and disciplines. From the voices of medical professionals and political representatives to surveillance studies and research papers spanning cardiovascular disorders to neurological symptoms, the compendium provides a rich tapestry of insights into the multifaceted nature of the crisis.

By delving into surveillance studies that analyze vaccine-associated mortality and examining the intricacies of vaccine development, this compendium underscores the importance of rigorous evaluation and transparency in public health interventions. Furthermore, it sheds light on the complex relationships between governments, pharmaceutical companies, and regulatory bodies, prompting critical reflection on the influence that shapes policy-making and public health decision-making processes.

As the author of this compendium, I recognize the limitations of any singular work and invite ongoing collaboration and dialogue to further deepen our understanding of the pandemic. It is my fervent hope that this compendium serves as a valuable resource for scholars, policymakers, and the general public, fostering informed discussions and guiding conscientious decision-making in navigating global health challenges.

In essence, this compendium stands as a testament to the enduring pursuit of truth and the unwavering commitment to transparency, accountability, and the protection of individual liberties in the face of complex global crises.

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